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HRP-591 - Protocol for Human Subject Research

Protocol Title:
Comparative effectiveness of social physical play and traditional exercise programming

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1.0 Objectives

1.1 Study Objectives

This study is designed to test the comparative effectiveness of two different exercise programs (PlayFit and Group Fitness) to inform our understanding how to best integrate community-based physical activity programs into routine settings for sedentary adults.

Fewer than 1 in 10 U.S. adults get the recommended amount of aerobic physical activity, greatly increasing their chances of heart disease, stroke, and other chronic conditions. Although physical activity (PA) reduces risk and treats many common health conditions, physicians are actually reducing how frequently they talk to patients about physical activity, largely in part, because they do not think their patients will not follow through with their recommendations. The core problem of disseminating physical activity remains the fact that so few people adhere to the recommendations long enough to benefit.

Although many barriers to physical activity are well known (e.g., time, cost), we believe that a key, modifiable, and underappreciated barrier is that most adults simply do not enjoy physical activity enough to do it regularly. While studies agree that people who enjoy exercise more are more likely to become active, no study to our knowledge has tested whether a program designed specifically to increase enjoyment, would lead to greater gains in activity and fitness.

We have developed and piloted such a program from 2015-2017, called PlayFit. The PlayFit exercise program involves adults coming together three times each week to play a range of sports, all modified to 1) reduce effort, 2) reduce injuries, and 3) reduce competitiveness. We intend to conduct a definitive study of the PlayFit program in a randomized controlled trial, assessing fitness gains in PlayFit compared to group fitness conditions.

Primary Objective: AIM 1: Test the impact of PlayFit, compared to a traditional Group Fitness exercise model, on fitness (V02max) and activity (MVPA) after 12 months. We hypothesize that PlayFit will improve fitness and activity greater than Group Fitness, and, that this will be mediated by greater gains in enjoyment and session adherence.

Secondary Objectives: AIM 2. Test the impact of PlayFit and Group Fitness on rates of injury, body weight, blood pressure, loneliness, depression, and anxiety. We hypothesize that PlayFit participants will see greater gains in these physical and mental health-related outcomes and have a similar injury rate.

Secondary Objectives: AIM 3: Test the feasibility (FEASIBILITY STUDY) of PlayFit to enhance physical activity levels among children age 10-12 and in the 6th or 7th grade, adults age 51-70 and adults being treated for major depressive disorder. We hypothesize that access to PlayFit 3-5 times weekly for 3 months will increase MVPA levels (versus baseline) for all participants and that objective measures of perceived enjoyment will be associated with attendance.

1.2 Primary Study

Endpoints RCT ONLY:

Aerobic Fitness (VO2max). Aerobic fitness will be assessed using a single maximal graded treadmill test, using a Bruce protocol and ECG or heart rate monitoring [1] using a metabolic measurement system such as a COSMED K5, Parvomedics or other system. The test will be terminated at a point of volitional fatigue, to ensure true VO2Max is achieved. Breath-by-breath VO2 is determine for each 3-minute stage

of the Bruce protocol. Three-minute stages ensure steady-state VO2 consumption (work output) has been achieved.

RCT + FEASIBILITY:

Minutes of Physical Activity (Moderate-Vigorous Physical Activity, MVPA) and Sleep.
The Actigraph GT3X tri-axial accelerometer will be used to measure total minutes of MVPA. Unlike a pedometer, the Actigraph can measure the intensity of PA and the frequency/pattern of activity over time. In the RCT, the Actigraph will be worn for 7 days at baseline, at the 6- and 12-month assessments and, for a random, stratified sample of 20% of study subjects, during PlayFit and Group Fitness exercise intervention activities, and data will be stored as 10-second averages. In the Feasibility studies, the Actigraph will be worn for 7 days at baseline and at the 6- and 12-week time points, and data will be stored as 10-second averages. Research assistants will ensure that participants understand how to accurately wear the accelerometer and we will contact participants during their accelerometer- wear time to ensure adherence. The Actigraph has been extensively validated and has been found to have high reliability [2, 3]. We will derive minutes per day each participant spends in moderate/vigorous (>2,019 counts/minute) activity, using cut-points derived by Matthew and colleagues [4]. Actigraph accelerometry will assess average daily time spent in sedentary activity (<100 counts per minute), light physical activity (100-1951 counts per minute), and moderate-vigorous physical activity (≥ 1952 counts per minute). MET level will be determined every 10 seconds, based on regression equations determined by Crouter and colleagues, who tested a range of sports (e.g., racquetball, basketball) that have short bursts of activity similar to the sports in PlayFit [5]. In addition, indices of sleep quantity and quality will be calculated using Actigraph software, including sleep duration (total sleep time), fragmentation, and minutes awake after sleep onset. These measures will be overseen by Dr. Liza Rovniak, an NIH-funded exercise scientist (R21HL118453, R00HL088017) [6, 7].

1.3 Secondary Study Endpoints

RCT + FEASIBILITY STUDY:

Adverse Events and Injuries. We will assess injuries and adverse events monthly during data collection contacts (online using REDCap), using a self- report measure adapted from one developed by Stathokostas and colleagues. The measure includes only 7 items and includes details on the body part injured as well as the severity of the injury (e.g., need to visit a doctor). The original measure by Stathokostas and colleagues was validated for use over a 12- month period, with high test–retest reliability (alpha of 0.76-1.00) and high validity, with all but type of injury (0.76) having κ coefficients greater than 0.80 [8].

Program Satisfaction. Satisfaction will be measured with a single question “How likely are you to recommend this program to a friend?”, scored on a 10-point scale. This single item question is used by many Fortune 500 companies, described in Harvard Business Review, as it is strongly predictive of future sales growth [9]. We will compare the percentage who rate their experience as 8,9, or 10, which is considered “highly satisfied” . Several face-valid questions are also asked to measure anticipatory enjoyment “are you looking forward” and “fun”.

Physical Activity Enjoyment Scale (PACES). The 18-item PACES scale is administered to measure perceived enjoyment of physical activity [10]. Sample items include “I enjoy it” and “I feel bored.” It has a high Cronbach’s alpha (>0.90) and is associated with future physical activity. Among children, we will use the shortened version (7-item) version of the PACES which has been validated and demonstrated excellent reliability among children [11].

Adherence. Attendance and Activity Tracking. As attendance is closely related to fitness gains in many studies of fitness programs [12], we will examine attendance in the Group Fitness and PlayFit groups using attendance logs maintained by research staff that supervise the groups.

Body Weight. Body weight and height will be measured by a research assistant using a portable, calibrated stadiometer (Tanita, Inc) [13]. Subjects will be clothed in a lightweight hospital gown and instructed to remove their shoes and to stand upright with their back and feet against the wall.

Blood Pressure. Blood pressure will be assessed according to the recommendations of the American Heart Association [14] . Resting blood pressure will be measured with the participant in a seated position using a professional, calibrated, aneroid sphygmomanometer. The average of three blood pressure measurements will be recorded, as our team has done in other studies [15].

5X Sit-to-Stand. The 5X Sit-to-Stand (5XSTS) will be administered by research study personnel at both the baseline and 12-week time points in the Older Adult Feasibility Study. Study subjects will be requested to perform the 5XSTS test as a measure of functional lower extremity strength.

Berg Balance Scale. The Berg Balance Scale (BBS) will be administered by research study personnel at both the baseline and 12-week time points in the Older Adult Feasibility Study. Study subjects will be requested to perform the 14-item BBS test as a measure of static balance and fall risk among older adults.

3-Minute Step Test. The YMCA 3-Minute Step Test (3MST) will be administered by research study personnel at both the baseline and 12-week time points in the Older Adult Feasibility Study. Study subjects will be requested to perform the test as a measure of cardiorespiratory fitness among older adults.

Physical Function. The 4-item, PROMIS Physical Function Questionnaire will be administered via automated, online REDCap online survey at both the baseline and 12-week time points in the Older Adult Feasibility Study.

Depression, Anxiety, Loneliness. We will use 11 self-reported questions to assess depression (4), anxiety (4), and loneliness (3). We will use depression and anxiety scales from the NIH-supported Patient Reported Outcomes Measurement Information System (PROMIS). Choi and colleagues observed high reliability (alpha > .91-.98) and construct validity (r = 0.84-0.90) with the PROMIS Depression measure and Beck Depression Inventory [16]. Other investigators have observed that subscales were valid compared to gold standard measures [17, 18] and responsive to treatments [19]. We will use a 3-item loneliness questionnaire (the Brief Loneliness Scale, Hughes, et.al 2004) which has high 12-month test-retest reliability (r = 0.73) [20] and is predictive of future functional decline and death [21]. Dr. Joshua Smyth, a clinical psychologist and Professor at Penn State with experience in clinical trials to improve anxiety and depression [22-25], will oversee the collection and analysis of these survey results. Subjects scoring 1 or more standard deviations above the mean T-score of 50 on the depression or anxiety scales will be contacted by research staff by phone within 48 hours of scoring to be informed of their score and advised to speak with their care provider concerning the results. Among adolescents we will instead use 16 items from the NIH-supported Pediatric Patient Reported Outcomes Measurement Information System (PROMIS) [26]. Among adults in the depression feasibility study, we will use the Hamilton Depression Rating Scale (HAM-D) to measure depression symptoms [27]. The HAM-D is valid and reliable for determining the severity of depression, for inclusion, as well as potential suicidality, which we will use to optimize safety. Anyone reporting a response to the HAM-D suicide question (question #3) of > 0 will be excluded and Dr. Saunders will contact the potential participant by phone to decide what should be done, if anything, clinically.

Basic Psychological Needs Satisfaction. Among adolescents in the feasibility study, we will use the Situational Needs Satisfaction scale to measure situational satisfaction of the needs for competence, autonomy, and relatedness. Children will respond to the stem “participating in this exercise program made me feel … ", followed by such items as “free to decide for myself what to do” (example from the Autonomy scale), “competent” (example from the Competence scale), or “involved with close friends”

(example from the Relatedness scale) [28].

Perceived Stress Scale (PSS-10). Among subjects in the Major Depressive feasibility study, we will use the PSS-10 to measure the acute perception of stress. The PSS is the most widely used instrument for measuring the acute perception of stress. The 10-item questionnaire assesses respondent feelings and thoughts during a specified period of time. Each item is scored from 0 (never) to 5 (very often) with a range of 0 to 40 for the total score of the scale. Higher scores indicate great perceived stress.

Generalized Anxiety Disorder Scale (GAD-7). Among subjects in the Major Depressive feasibility study, we will use the GAD-7 to identify probable cases and assess anxiety symptom severity. The GAD-7 is a 7-item self-administered instrument frequently utilized in primary care settings (including Penn State) that uses some of the DSM-V criteria for Generalized Anxiety Disorder (GAD) to identify probable cases and assess anxiety symptom severity. Responses are on a 4-point Likert scale ranging from 0 equating to "not at all" to 3 equating to "almost every day." The total score ranges from 0 to 21 with higher values indicating more severe anxiety.

Patient Health Questionnaire (PHQ-9). Among subjects in the Major Depressive feasibility study, we will use the PHQ-9 to measure depressive symptoms. The PHQ-9 is a standard, brief measure of depressive symptoms, consists of 20 items and has a total score ranging from 0 to 60. Minimum scores of 16 indicate clinically significant levels (i.e., mild) of depressive symptoms.

World Health Organization Disability Assessment Schedule (WHODAS 2.0). Among subjects in the Major Depressive feasibility study, we will use the WHODAS 2.0 to measure health and disability at population level or in clinical practice across six domains (Cognition, Mobility, Self-care, Getting along, Life activities, Participation). The WHODAS is a practical, generic assessment instrument that can measure health and disability at population level or in clinical practice across six domains. For all domains, it provides a profile and a summary measure of functioning and disability that is reliable and applicable across cultures, in all adult populations.

Behavioral Regulations in Exercise Questionnaire (BREQ-3). Among subjects in the Major Depressive feasibility study, we will use the BREQ-3 to measure external, introjected, identified and intrinsic forms of regulation of exercise behaviour. The Behavioural Regulation In Exercise Questionnaire (BREQ) and its subsequent modifications have become the most widely used measures of the continuum of behavioural regulation in exercise psychology research. The original BREQ (Mullan, Markland & Ingledew, 1997) was developed to measure external, introjected, identified and intrinsic forms of regulation of exercise behaviour based on Deci & Ryan's (1985, 1991) continuum conception of extrinsic and intrinsic motivation.

Perceived Environmental Supportiveness Scale (PESS). Among subjects in the Major Depressive feasibility study, we will use the PESS to measure perceptions of need support provided by exercise practitioners to exercise clients/participants. The PESS is used to assess perceptions of need support provided by exercise practitioners to exercise clients/participants. The measure has been adapted to assess need support in other contexts, including exercise classes and support provided by coaches.

Exercise Motives and Gains Inventory (EMGI). Among subjects in the Major Depressive feasibility study, we will use the EMGI to measure the different beliefs, motives and gains associated with physical activity engagement and is commonly used in exercise research.

Locus of Causality for Exercise Scale (LCE). Among subjects in the Major Depressive feasibility study, we will use the LCE to measure the extent to which individuals feel that they freely choose to exercise rather than feeling that they are required to for some reason. The Locus of Causality for Exercise Scale (LCE) is a brief, three-item scale designed to assess the extent to which individuals feel that they freely choose to exercise rather than feeling that they are required to for some reason. Responses to the LCE are scored on a Likert-type scale ranging from 1 (strongly disagree) to 7(strongly agree). High scores indicate greater self-determination or a more internal perceived locus of causality and low scores less self-

determination.

RCT ONLY

Lubben Social Network Scale (LSNS6). The LSNS6 is a brief (6-item) measure of the extent of a person's social engagement with both family (3 items) and friends (3 items) [29]. The LSNS6 has high test-retest reliability (alpha = 0.83) [29] and has been observed to predict future levels of dementia and depression [29-33].

Self-Reported Physical Activity. The International Physical Activity Questionnaire (IPAQ) is a comprehensive assessment of moderate- and vigorous-intensity physical activities and sedentary behavior in adults [34, 35]. The 31-item long-form was designed to provide an evaluation of physical

activity in key domains: work, household, transportation, and leisure. A reference period of the "last 7 days" is used. Reliability and validity testing was conducted with 2,700 adults (18-55 years old) in 12 countries. Eight-day test-retest reliability for total physical activity recall was very good with a median coefficient of about .80. Criterion validity using Actigraph accelerometers was acceptable with a median coefficient of .40 [35].

Exercise Self-Efficacy. Self-efficacy for exercise will be measured with a 5-item self-efficacy measure has an internal consistency of 0.76 and test-retest reliability over a 2-week period of 0.90 [36, 37].

The Preference for and Tolerance of the Intensity of Exercise Questionnaire. The intensity of exercise that individuals prefer and the intensity that they can tolerate will be measured with a 16-item measure.

Affective Exercise Experiences Questionnaire. The 36-item Affective Exercise Experiences Questionnaire assess the constructs within a conceptual model, according to which core affective exercise experiences (pleasure-displeasure, energy-tiredness, calmness-tension) are influenced by six antecedent appraisals and, in turn, shape attraction or antipathy towards exercise.

Perceived Motor Competence Questionnaire for Children. Perceived motor skill competence will be measured with the 24-item Perceived Motor Competence Questionnaire for Children. We are using the PMC-C because there are no available questionnaires among adults to test perceived motor skill competence. It is often difficult to use adult questionnaires with children due to reading/comprehension differences, but using a child questionnaire among adults should pose none of these problems and still allow us to tap into the same constructs of locomotor and object control motor skills.

2.0 Background

2.1 Scientific Background and Gaps

There is great potential to reduce deaths in the US by increasing PA levels. Adults know that PA is important for their health though, despite that understanding, fewer than 10% of adults get enough exercise [38, 39]. As a result, more than 300,000 U.S. adults die prematurely each year from a lack of PA [40]. These low rates are troubling because PA appears to be highly effective for reducing risk for several diseases perhaps most notably CVD [41], which continues to be the leading cause of death for both men and women in the U.S. Fortunately, even small increases in PA—as little as 15 minutes per day—have been associated with large reductions in risk for CVD [41]. In addition, a 2013 summary of 16 meta-analyses concluded that exercise was as effective as medications for secondary prevention of coronary heart disease and more than five times as effective as medications for stroke [42]. The benefits of increasing PA extend well beyond CVD. A 2016 systematic review showed that physical activity levels were inversely related to all five major diseases that were studied: breast cancer, colon cancer, diabetes, ischemic heart disease, and ischemic stroke [43]. Collectively, these findings make it appear as though there is another medication available (i.e., exercise) for preventing CVD and other chronic conditions, and yet, fewer than 1 in 10 people who could benefit from taking it, actually do so.

Few people exercise regularly, in large part, because they do not enjoy the experience. Adults understand that exercise is important for their health, yet they choose overwhelmingly not to exercise. Assuming that cost is not a major barrier (55 million Americans belong to a fitness center) [44], nor is time (U.S. adults watch an average of 2.7 hours of TV each day) [45], nor travel (most adults can either walk or have fitness equipment at home), we believe that a key, unexplored driver is that people do not enjoy the moment-to-moment experience of physical activity enough to stick with it. Studies consistently observe that people who enjoy PA are more likely to become and stay active [10, 37] . For example, a recent intervention among 448 adults observed that increases in perceived enjoyment were stronger predictors of future PA than increases in self-efficacy [37] , concluding that "interventions should perhaps initially focus on increasing enjoyment of physical activity". This research is leading investigators, including Dr. David Conroy (Co-I) [46-48], to examine the impact of modifying the affective response

(including perceived enjoyment) as a way to increase PA. To our knowledge, no study among adults has manipulated PA enjoyment, in a clinical trial, to understand its impact on PA. What we propose, therefore, will advance our understanding of the role of perceived enjoyment as a mediator of PA.

Social physical play, while common in childhood, has been little studied as an adult PA intervention. Social physical play has the potential to enhance adherence by addressing two key aspects of human psychology: First, all humans play, though few adults play social physical games. A 2015 survey observed that 73% of adults played sports when younger, though only 25% currently played sports [49]. Our team recently observed, among 183,341 adults, that those whose participated in social physical play were 40% less likely to report mental distress [50]. Second, humans are social. As an activity, socializing was second in positive affect only to intimate relations in a 2004 study [51]. Since 1965, however, time spent

socializing has declined dramatically [52] and, between 1985 and 2004, the percentage of adults with no close friends doubled from 10% to 24%[53] . These studies suggest that physical activities that include meaningful social interactions, including play, have a great potential for increasing engagement and long-term adherence, and possibly even improving mental, and not just physical health.

Theoretical Framework for Using Perceived Enjoyment to Drive Increases in Fitness. As an affective factor, enjoyment can influence behavior through the experience and expectation of pleasure or displeasure [54, 55]. The idea that enjoyable PA can lead to sustained PA adherence is consistent with self-determination theory [56] and hedonic theory [54], which maintain that individuals are motivated by behaviors that are rewarding. Indeed, enjoyment of physical activity appears to be a key predictor of both PA initiation [37, 57-60] and PA behavior over time, particularly in the context of behavioral interventions [37]. Collectively, there is a compelling body of research showing that perceived enjoyment is an important mediator of PA adherence [10, 37]. In a recent paper, Lewis and colleagues observed, among 448 adults participating in a clinical trial, that enjoyment was a stronger predictor of future activity than self-efficacy [37]. They concluded that "interventions should perhaps initially focus on increasing enjoyment of physical activity" [37]. These authors also noted that since enjoyment could be considered an intrinsic trait, and therefore a potential challenge to change a person's perception of PA as enjoyable, researchers and practitioners "need to be creative regarding how to work with individuals to improve their enjoyment" and "should encourage people to try a variety of activities" [37].

2.2 Previous Data

Middle-aged adults are quite interested in modified sports fitness program. In two primary care practices in Central Pennsylvania in 2015, we anonymously surveyed 540 patients in the office before their visit. The response rate was 90.0% and most (59.6%) of adults 50 years of age or younger were interested in the program, which was described as "a regular fitness program where people your own age played games, such as softball, floor hockey and soccer, that were made to be easier to play and less competitive". After adjusting for potential confounders, female patients and those with hypertension, high cholesterol or obesity were no less interested in participating [61].

A pilot study in 2016 observed that the activities are moderate-vigorous and enjoyable. We designed PlayFit in 2015 after observing the popularity of Pickleball—a version of tennis modified to reduce effort, with a smaller court and plastic ball [62]. Using this model, we settled upon a design for a physical activity program that consisted of five modified sports, all of which could be rotated in order to provide variety and minimize overuse injuries. We first recruited 14 adults for pilot studies in which we modified 10 commonly-played sports to reduce effort (e.g., smaller court, lightweight volleyball for soccer) and to maximize positive playful social interactions (e.g., choosing sides randomly each session, switching players if scores became lop-sided, minimizing physical contact and insisting that all players must touch the ball to score).

In 2016, 22 adults participated in PlayFit for 3 months. Five sports (e.g., kickball) were removed due to inadequate energy expenditure, leaving 5 (soccer, ultimate Frisbee, ultimate football, team handball and netball) that have a similar set of rules and, based on accelerometry, at least 88% of time was in the moderate-vigorous range and 24% in the vigorous range. Satisfaction, measured after each session using the Net Promoter Score [9], was high (7.7-8.4 out of 10). The comments were quite positive, including: "Oh my gosh, I'm sweating buckets!! That's the best part, aside from the required rule to pass to all players-Yay teamwork!", "It was really fun. There were enough rules to make sense but not enough to take away from the leisure activity", and "Game was really fun. There was a great amount of teamwork needed with this game" (see PlayFit Comments table above). This positive social experience appears similar to the results of Band Together [63], a social strength training program that our team designed, now being studied in a 2100-person, PCORI-funded, clinical trial.

2.3 Study Rationale

Study Design. We propose a 12-month randomized trial to answer the following question for both patients, health care providers and fitness center directors: "What group exercise program will best promote long-term adherence and fitness?" The design consists of two activity conditions (Group Fitness, PlayFit). We hypothesize that, by enhancing perceived enjoyment and thereby attendance and adherence, PlayFit will lead to greater gains in fitness, and better physical and mental health than a traditional Group Fitness program. This study is built upon prior work showing that while low PA levels greatly increase risk of diseases such as CVD [41] and that increasing PA significantly reduces risk for several chronic conditions [43], fewer than 10% of adults actually meet PA guidelines [64, 65]. As perceived enjoyment consistently predicts adherence [10, 37], the overall body of evidence raises the question, not yet studied: "If adults are offered access to an exercise program designed to maximize enjoyment, would adherence and fitness increase?" The dominant models for PA promotion focus on enhancing motivation via goal-setting, tracking progress, providing feedback, and overcoming barriers to physical activity [7, 66]. The question to be answered in this study is complementary to that line of work, but expands the range of potential influences to include type of the physical activities themselves (designed to be enjoyable forms of "play" vs. not). As group fitness programs include "group" activities, we have included a Group Fitness condition to control for the effect of exercising in a group setting.
Group Fitness activities, however, do not typically include much interaction between participants. PlayFit, in contrast, includes a more intensive social interaction by focusing on team-based gameplay, yet designed to reduce competitiveness and maximize enjoyment. In most group fitness classes, social interaction is optional and the activities are not typically designed to be inherently enjoyable. PlayFit, by comparison, requires social interaction and taps into a powerful source of enjoyment - play. A worldwide survey by the furniture company IKEA observed that physical play was rated, by children, as more enjoyable than even television or video games [67]. Despite the importance of play to the human experience, few adults play sports [49] and few studies noted in meta-analyses of physical activity have applied aspects of play to adult physical activity promotion [68].

What could occur if PlayFit outperforms Group Fitness classes? We believe that three things would occur. First, fitness centers would offer programs such as PlayFit, in order to maximize social engagement, which fitness centers already use to help members make new friends which help people maintain their membership longer [69]. PlayFit is designed to be used on a basketball court, which is present in many fitness centers. We would make the protocol publicly available, in the public domain for free, to encourage its use. Second, it may lay the foundation for changing advice to patients from providers. Rather than focusing simply on the amount of activity and intensity of activity, providers could encourage patients to focus on how enjoyable the activity is to their patients. Third, it may lay the foundation for a change in exercise prescriptions to include a focus on enjoyment. At the present time, exercise prescriptions focus on frequency, intensity, type (moderate v. vigorous) and time (duration) [70]. Fourth, the design elements adapted for PlayFit—modifying where the intervention takes place, targeting whom the intervention takes place with, and altering what is done during the intervention— could be applied to other preventive health behaviors, such as healthy eating, to further refine interventions [42, 71-74].

Can PlayFit improve physical activity across the lifespan and in among groups with specific barriers to physical activity? We propose conducting a feasibility study (which we refer to in this document as "Feasibility Study") to understand whether PlayFit is feasible for groups of people who may also benefit from increasing physical activity, but who are not part of the RCT of PlayFit versus Group Fitness. The rationale for these specific groups is as follows. First, older adults have the most to gain from physical activity but are the least active, so modifying PlayFit for this population has the potential to improve population health. Second, the greatest decline in physical activity during life is between ages 8-11 and ages 11-14, where there is a 75% decline in minutes of activity [38], making this a critical period for

intervening to enhance physical activity. Third, while exercise has been proven repeatedly to improve mental health outcomes in patients with major depressive disorder (MDD), those patients have unique barriers to performing new activities that often make them unwilling to start a physical activity program, despite how much it may help them. To answer those questions we will enroll up to 150 participants, up to 50 adolescents ages 10-12 and in the 6th or 7th grade, up to 50 adults age 51-70 and up to 50 adults currently being treated for major depressive disorder. Adults of each group will be invited to participate in a focus group, to inform changes to PlayFit to adapt it to the specific target population. All 50 of each group will then be given access to the modified version of PlayFit, to be held several times each week for 3 months.

3.0 Inclusion and Exclusion Criteria

3.1 Inclusion Criteria

Focus Groups

- Age 21+.
- Sedentary, defined as less than 90 minutes of moderate or vigorous activity each week.

Feasibility Study:

- Age 10-12 and in the 6th or 7th grade for Adolescent Feasibility Study
- Age 51-70 for Older Adult Feasibility Study.
- Age 18+ being treated (medicines or talk therapy, as in Mental Health History Measure) for major depressive disorder (MDD) and with at least mild levels of depression (score of ≥ 8), as measured by the Hamilton Rating of Depression (HAM-D), for Major Depression Feasibility Study
- For the Major Depressive Disorder feasibility study, all participants will be required to be categorized as Sedentary, defined as less than 90 minutes of moderate or vigorous activity each week. This will be determined using Physical Activity items from the National Health Interview Survey [75].
- For the Older Adult feasibility study, all participants will be required to be categorized as Sedentary, defined as less than 60 minutes of moderate or vigorous activity each week. This will be determined using Physical Activity items from the National Health Interview Survey [75].

- For the Adolescent feasibility study, all participants will be required to be categorized as Sedentary, defined as less than 60 minutes of moderate or vigorous activity each day. This will be determined using Physical Activity items from the National Health Interview Survey [75].

RCT

- Age 18-50.
- Sedentary, defined as less than 90 minutes of moderate or vigorous activity each week. This will be determined using Physical Activity items from the National Health Interview Survey[75] .
- Must have access to the Internet at home.

3.2 Exclusion Criteria

Focus Groups

- Potential subjects who cannot read and speak English.
- Health care provider told subject they had a heart condition and should only do physical activity recommended by a doctor.

Feasibility Study

- Physician, Nurse Practitioner or Physician's Assistant is unwilling to sign permission for subjects with between 2 and 4 risk factors for heart disease, of the following 5 (sedentary lifestyle, smoking, high blood pressure, high cholesterol, early heart disease in a family member), or unwilling to sign permission for potential subjects who disclose any of the following COVID-19-specific items during screening (family member with current or past COVID-19 infection, moderate-to-severe asthma, takes medication for or has a medical condition that weakens the immune system, symptoms of COVID-19 infection).
- A history of Heart disease, diabetes, angina, heart failure, stroke, mini-stroke (transient ischemic attack), weak or failing kidneys
- Symptoms of chest pain, dizziness, loss of consciousness, a bone or joint problem that can be worsened with physical activity or being diagnosed with a heart condition by a doctor, based on questions from the Physical Activity Readiness Questionnaire (PAR-Q) [76]
- Inability to read and speak English.
- Pregnant or planning to become pregnant in the next four (4) months.
- Planning to have surgery or move in the next four (4) months.
- Suicidality, schizophrenia, psychosis or bipolar disease, among subjects in the feasibility study for subjects with major depressive disorder (MDD), based on a affirmative response (>0) to question 3 on the Hamilton Rating Scale for Depression (HAM-D) [27].

RCT

- Physician, Nurse Practitioner or Physician's Assistant is unwilling to sign permission for subjects with between 2 and 4 risk factors for heart disease, of the following 5 (sedentary lifestyle, smoking, high blood pressure, high cholesterol, early heart disease in a family member), or unwilling to sign permission for potential subjects who disclose any of the following COVID-19-specific items during screening (family member with current or past COVID-19 infection, moderate-to-severe asthma, takes medication for or has a medical condition that weakens the immune system, symptoms of COVID-19 infection). The same rule will apply to household members, who will need the same permission from a health care provider is 2, 3, or 4 cardiac risk factors are present.
- A history of Heart disease, diabetes, angina, heart failure, stroke, mini-stroke (transient ischemic attack), weak or failing kidneys
- Symptoms of chest pain, dizziness, loss of consciousness, a bone or joint problem that can be worsened with physical activity or being diagnosed with a heart condition by a doctor, based on questions from the Physical Activity Readiness Questionnaire (PAR-Q) [76]
- Four or more risk factors for coronary artery disease, of those listed above (sedentary lifestyle, smoking, high blood pressure, high cholesterol, early heart disease in a family member).
- Age over 50.
- Participating in another research project involving physical activity or weight loss.
- Planning to have surgery or move in the next year.
- Potential subjects who cannot read and speak English.
- Pregnant or planning to become pregnant in the next year
- If blood pressure at the Baseline Visit is > 160 systolic OR >100 diastolic OR heart rate is > 120 bpm, research staff will suggest the individual to see a PCP to control their blood pressure or heart rate, and if they would like to still participate in our study they can be tested again in the future.
- Unwilling to wear a face covering during the mandate period (COVID-19).

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

It is possible we will withdrawal participants from the study if they are unwilling to follow COVID-19-

related safety procedures during the mandate, become injured and cannot exercise or if they are asked by their Primary Care Provider to suspend exercise. The Principal Investigator reserves the right to remove a participant from the study for any reason, based on their discretion, particularly a belief that continued participation exposes them to unnecessary risk. Also, participants have the right to withdraw themselves at any time and halt all study-related activities permanently.

Other withdrawal criteria include: unwillingness to follow exercise protocol during sessions, unwillingness to complete the baseline assessment survey and/or return the accelerometer to study staff, withdrawal of consent by subject, development of a medical problem that would exclude them from the study (e.g., heart disease).

3.3.2 Follow-up for withdrawn subjects

If the participant contacts us that they want to withdraw from the study, we will ask them to write a note and email it or put it in the mail documenting their desire to withdraw. Once we receive the letter, subjects will be withdrawn immediately. Subjects withdrawn will not have additional intervention or data collection activities schedule. They will not be replaced. For the focus groups, we will replace subjects who are withdrawn.

4.0 Recruitment Methods

4.1 Identification of subjects

We will send letters to patients of the Penn State Health, who reside in the zip codes of interest. Mailing lists will be generated by EIM. Patients age 18-50 who reside in a 10 mile radius around the exercise sites will be sent a letter. We, too, will generate mailing lists by EIM for recruitment of patients aged 51-70 years old. We will also place advertisements in newspapers, Facebook pages and communications from township park departments, schools or other community messaging print medium. We will also post printed advertisements (i.e., flyers) in public spaces frequented by potential participants. We will also use radio advertisements and advertisements when callers are on hold with the phone system phone system at Penn State Hershey. Of note, there is no specific maximum age, but participants to date in the pilot work have been under 50 years of age. If older participants hear about the study, they will be screened and treated the same as those who respond to a letter and are younger. For focus groups, participants in our prior research projects of PlayFit, who have previously given us permission to contact them for future studies, may also be called by phone to seek their participation.

We will also mail to potential subjects using a third-party list from a marketing company, such as Lorton Data, limited to those that live nearby the exercise site. When possible we will partner with community organizations that can send IRB-approved recruitment letters to members of their community, such as to parents of school students in the case of the Middletown Area Recreation Alliance.

4.2 Recruitment process

Interested participants will call our toll-free number and, if interested, be screened.

4.3 Recruitment materials

RCT:
Recruitment letter.

Feasibility Study:
Recruitment letter. We have created recruitment letters for each feasibility study (Adolescent, Depression, and Older Adult). These will be mailed to Penn State Health (PSH) patients identified by EIM who meet the age criteria (PSH patients aged 51-70 for the Older Adult Feasibility Study, PSH patients aged 10-12 for the Adolescent Feasibility Study, and PSH patients aged 18 or older meeting the inclusion criteria for the Depression Feasibility Study). More letters will need to be mailed for the Depression Feasibility study, are rates of depression among clinical populations are approximately 10% (6% for men, 12% for women). In the interest of maximizing recruitment success, we have created more than one version of recruitment materials for the Depression Feasibility study. Specifically, two different versions of the recruitment letter were developed; the first letter uses language focusing on “depression” and “mood” improvement while the other letter focuses more generally on “stress.” There is still some stigma related to labels for mental health disorders such as “depression,” which may limit the response rate of otherwise interested patients. However, it is also possible that patients experiencing depression may also be uniquely interested in the study due to the direct language surrounding depression/mood relief in the letter. Alternatively, “stress” is a more general term, that while related to depression, is universally experienced and carries less stigma. Overall, we do not know whether directly discussing depression versus stress diminishes or aids recruitment. We will send both letters simultaneously to maximize recruitment success in the shortest possible time and ultimately learn which messaging format is most effective via comparison of response rates; this will inform our future approaches to recruitment messaging. Recruitment letters for the Depression Feasibility study will include signature from Brandon Auer, Ph.D, Recruitment letters for the Adolescent Feasibility study will include signature from Matthew Ladwig, Ph.D.

4.4 Eligibility/screening of subjects

Focus groups

Interested subjects will be screened by phone by research staff who will read the phone screening document which will ensure eligibility and will inform them of study procedures. If eligible and interested in participating, they will be scheduled to attend one of the focus groups.

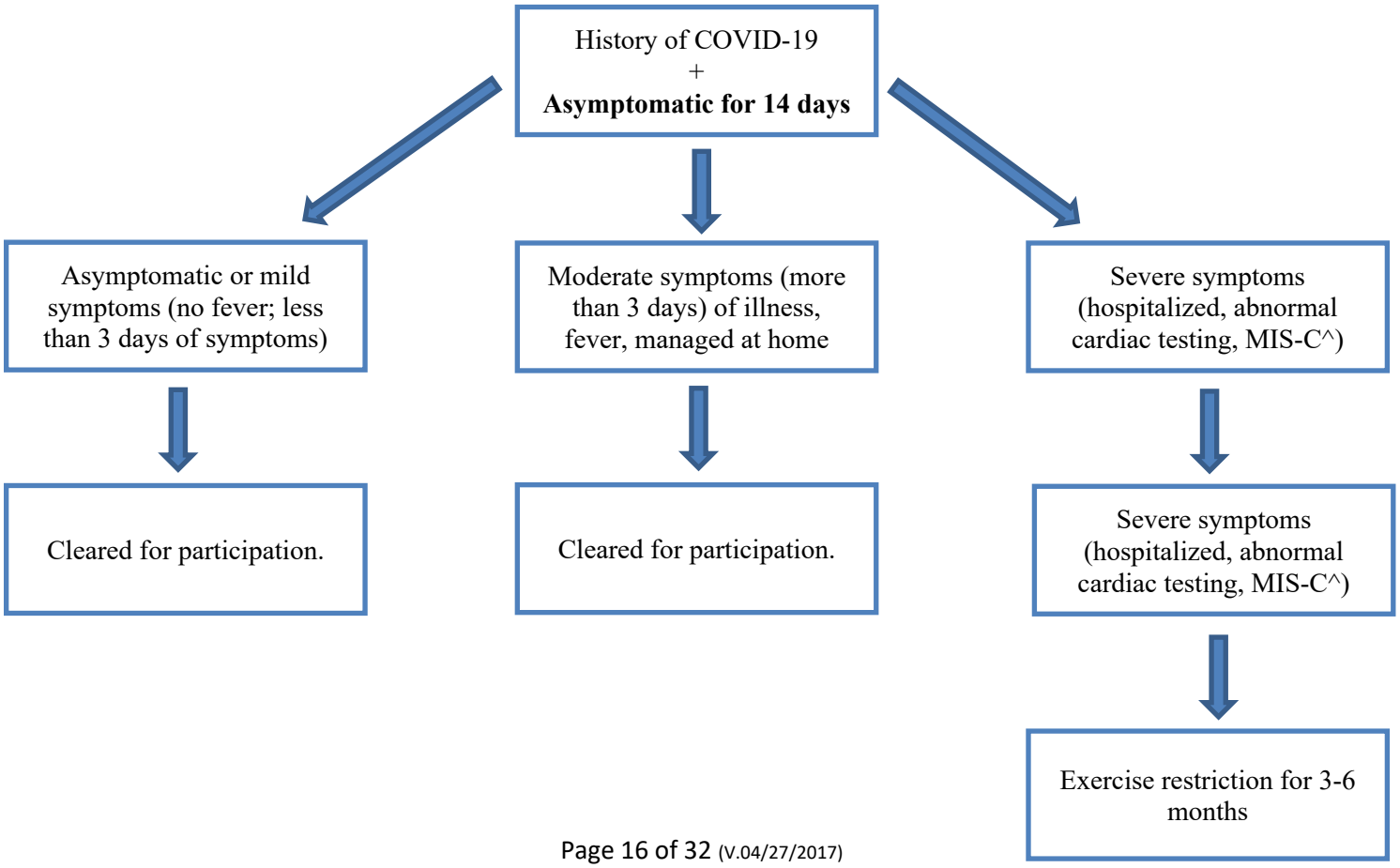
RCT

Interested individuals who initiate contact with research staff via email—following receipt of a recruitment letter—will first be provided with an expectations/project summary document outlining next steps associated with the research. Those who initiate contact with research staff via phone call will be provided with the project summary document at the conclusion of the screening phone call, if deemed eligible. Individuals who remain interested in participating will be screened by phone by research staff who will read the phone screening document which will ensure eligibility and will inform them of study procedures. If eligible with continued interest in participating, they will be asked to sign consent electronically prior to the baseline visit, and then collect measurements at the baseline visit.

COVID-19 Design Modifications

Interested subjects will be screened by phone by research staff who will read the COVID-19-specific phone screening content which will ensure eligibility and will inform them of COVID-19-specific study procedures. If the interested subject discloses a diagnosis of or positive test for COVID-19 within the previous 6 months of the phone screening, research staff will inform them of study procedures related to the Return to Play After COVID-19 screening algorithm (Figure 1). If the interested subjects indicates a negative response relating to diagnosis of or positive test for COVID-19, research staff will read the COVID-19 Supplemental Questionnaire which will ensure eligibility.

Figure 1. Return to Play after COVID-19 Algorithm



Algorithm based on current recommendations from: 1) PlayFit Study DSMB Members; 2) Study Physician, Dr. Matthew Silvis, MD; and 3) the ACC, AMSSM, and NFHS. These recommendations are subject to change as more evidence on COVID-19 myocarditis becomes available. Any subject who develops signs of clinical instability should be directed to the emergency department. If never symptomatic, the 14-day period begins at the time of a positive test. If there is return of any symptoms, the 14-day asymptomatic period restarts.

Feasibility Study

Interested subjects will be screened by phone by research staff who will read the phone screening document which will ensure eligibility and will inform them of study procedures. If eligible and interested in participating, they will be asked to sign consent electronically prior to attending the initial in-person visit.

5.0 Consent Process and Documentation

5.1 Consent Process

5.1.1 Obtaining Informed Consent

5.1.1.1 Timing and Location of Consent

RCT + Older Adult, Major Depressive Feasibility Studies

Participants will individually review the consent form with one of the research coordinators via phone call. Research coordinator will individually review the consent form with participants as outlined per Penn State University's eConsent procedures and answer any questions; individuals will be requested to sign electronically. Research coordinator will provide a signed copy of the consent form via email at the conclusion of the phone call in order to allow participants to keep for their records. Dr. Sciamanna will not participate in the consent process. For adolescent participants, a parent or guardian will need to be present throughout the full duration of the phone call to review and sign the consent form. In addition, the adolescent child will provide assent in the same form.

Adolescent Feasibility Study

Potential participants will individually review the consent form with one of the research coordinators via phone call. Of note, research coordinator will email a copy of the consent form to the individuals (parent/guardian for child and child) prior to the phone call to assist with the phone call review and provide the individuals with ample additional time to review the form prior to signing at the first in-person visit, should they wish. Research coordinator will individually review the consent form with potential participants and answer

any questions. Research coordinator will provide a consent form at the project site, and the individuals will be asked to sign. A copy of the consent form will be provided to participants to keep for their records. Dr. Sciamanna will not participate in the consent process.

5.1.1.2 Coercion or Undue Influence during Consent

RCT
As outlined per Penn State University's eConsent procedures, participants will be emailed a copy of the consent form upon the start of the phone call review. They will be encouraged to ask questions during the consent process on a one on-one basis with the study staff. They can withdraw from the study at any time. Dr. Sciamanna will not participate in the consent process.

5.1.2 Waiver or alteration of the informed consent requirement

The study team is requesting a waiver of informed consent to allow for recruitment from clinic schedules and to access the subjects' medical charts.

5.2 Consent Documentation

5.2.1 Written Documentation of Consent

RCT + Older Adult, Major Depressive Feasibility Studies
Consent will take place via phone call as outlined per Penn State University's eConsent procedures. Research coordinator will individually review the consent form with participants, answer any questions, and obtain electronic written consent. A copy of the consent form will be provided to participants to keep for their records.

Adolescent Feasibility Study
Consent review will take place via phone call. Research coordinator will individually review the consent form with the individuals (parent/guardian for child and child) and answer any questions. Research coordinator will provide a consent form at the project site, and the individuals will be asked to sign. A copy of the consent form will be provided to participants to keep for their records.

Older Adult Feasibility Study
Research coordinator will individually review the consent form with participants, answer any questions, and obtain signed written consent. A copy of the consent form will be provided to participants to keep for their records.

5.2.2 Waiver of Documentation of Consent (Implied consent, Verbal consent, etc.)

Adults with Major Depression
Given the minimal risk nature of the intervention we will, as in past studies of PlayFit, use a Summary Explanation of Research document to consent participants. The highest risk part of the PlayFit RCT, the maximal fitness test, will not be performed in the Feasibility Studies, reducing risk significantly. Effort level will slowly be increased (by increasing the duration of play periods) over the first 4-6 weeks to accommodate for low levels of fitness at baseline.

5.3 Consent – Other Considerations

5.3.1 Non-English Speaking Subjects

Not applicable.

5.3.2 Cognitively Impaired Adults

Not applicable.

5.3.2.1 Capability of Providing Consent

Subjects must be able to answer all questions during the phone screener. Those who cannot answer screener questions clearly and reliably will be assumed to be incapable of providing consent.

5.3.2.2 Adults Unable To Consent

Not applicable. We will only be enrolling subjects who can provide their own consent.

5.3.2.3 Assent of Adults Unable to Consent

Not applicable. We will only be enrolling subjects who can provide their own

consent.

5.3.3 Subjects who are not yet adults (infants, children, teenagers)

5.3.3.1 Parental Permission

For the Adolescent Feasibility project only, parental consent is required, as subjects will be ages 10-12 and in the 6th or 7th grade.

5.3.3.2 Assent of subjects who are not yet adults

For the Adolescent Feasibility project only, participants (ages 10-12 and in the 6th or 7th grade) will be required to provide assent. In all other projects, this will be not applicable as we will be only enrolling adults.

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of

PHI Check all that apply:

☐ **Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study.** *[Mark all parts of sections 6.2 and 6.3 as not applicable]*

☒ **Authorization will be obtained and documented as part of the consent process.** *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*

☒ **Partial waiver is requested for recruitment purposes only (Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Full waiver is requested for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*

☒ **Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained).** *[Complete all parts of sections 6.2 and 6.3]*

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2.1.1 Plan to protect PHI from improper use or disclosure

Information is included in the "Confidentiality, Privacy and Data Management" section of this protocol.

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

Identifiers will be kept until all data is analyzed

6.2.2 Explanation for why the research could not practicably be conducted without access to and use of PHI

Clinic directors for the Departments of Family and Community Medicine and Medicine will create lists of patients who meet the age cutoff (Ages 10-12 and in the 6th or 7th grade for Adolescent Feasibility project and ages 18 and over for other parts of the project) in the desired geographic area. They will provide us names and mailing address so research staff can send recruitment letters. We need to collect personal health information from the participants during the phone screening to determine eligibility for the study.

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Since this is an exercise study we want approval from the participant's primary care provider to minimize any health risks. We will ask their Primary Care Provider to provide permission to participate, if their answers on the screener, about their symptoms and past medical history, suggest that physical activity may harm them.

6.3 Waiver or alteration of authorization statements of agreement

Protected health information obtained as part of this research will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other permitted uses and disclosures according to federal regulations.

The research team will collect only information essential to the study and in accord with the 'Minimum Necessary' standard (information reasonably necessary to accomplish the objectives of the research) per federal regulations.

Access to the information will be limited, to the greatest extent possible, within the research team. All disclosures or releases of identifiable information granted under this waiver will be accounted for and documented.

7.0 Study Design and Procedures

7.1 Study Design

RCT
We propose a 12-month randomized trial to answer the following question for both patients, health care providers and fitness center directors: "What group exercise program will best promote long-term adherence and fitness?" The design consists of two activity conditions (Group Fitness, PlayFit). We hypothesize that, by enhancing perceived enjoyment and thereby attendance and adherence, PlayFit will lead to greater gains in fitness, and better physical and mental health than a traditional Group Fitness program [77, 78].

Eligible subjects will be randomly assigned to two exercise conditions, group fitness and PlayFit. They will then be offered up to 4 scheduled sessions of each exercise program per week. They will complete fitness testing and baseline, 6 and 12 months. We hypothesize that subjects in the PlayFit condition will experience greater gains in fitness (measured by V02max) and that this will be due to the higher levels of satisfaction with PlayFit, which will lead to greater levels of attendance and thereby, fitness.

Of note, each participant can, if they choose, have one additional person from their household join the project and participate in the intervention but not in the fitness testing or measures at baseline, 6-, and 12-months. This is designed to reduce nonadherence and to increase enrollment as many people join fitness programs with a household contact and randomizing them to different conditions is impractical. These individuals are referred to in this protocol as a "HOUSEHOLD MEMBER" to denote their different level of involvement.

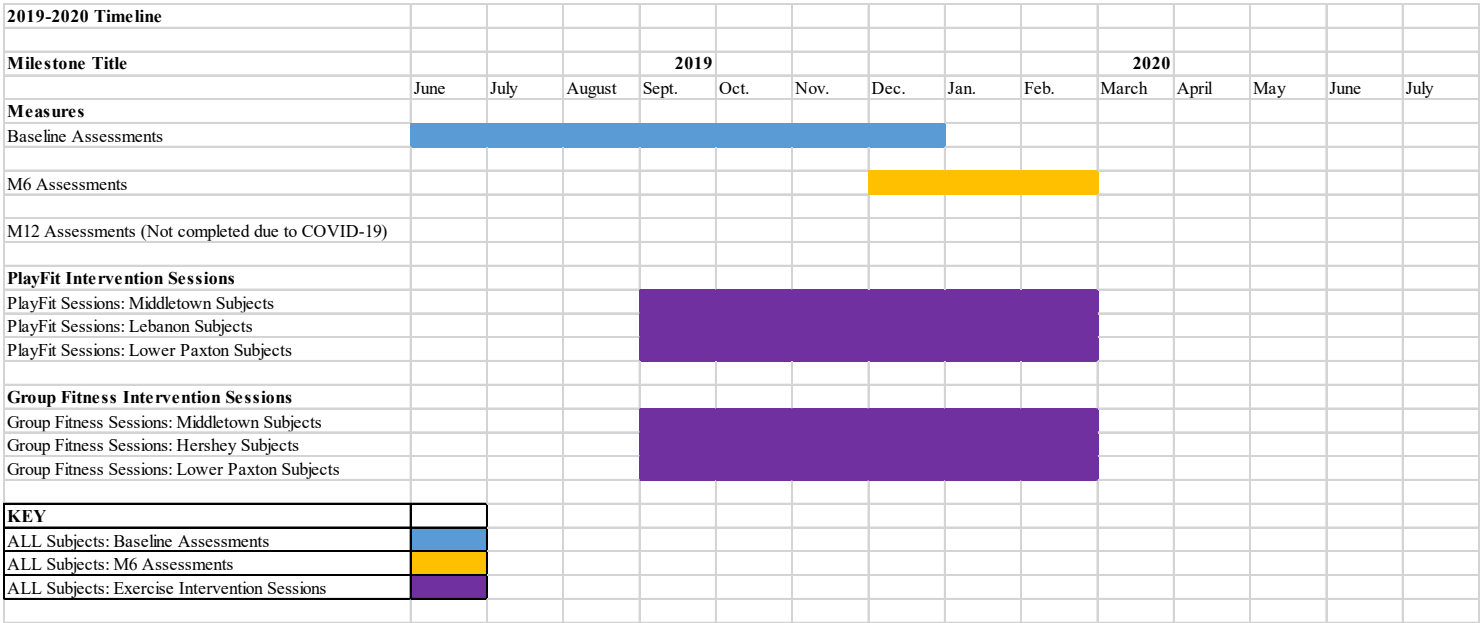
RCT: COVID-19 Design Modifications
We have implemented modifications to the PlayFit study and the operations of delivering the in-person interventions to adhere to the safety guidelines and considerations outlined by Penn State University, federal, state, and local governments, the CDC, and Pennsylvania DOH, to help our team prepare for a reality in which many of the COVID-related mandates may remain for the foreseeable future. The research design modifications we propose aim to: 1) examine the feasibility of applying the recommended social distancing measures to the already typically socially distanced PlayFit sport-games (i.e., designed to be non-contact, with passes being made between distanced individuals); and 2) test the impact of applying

health and safety protocol measures to the delivery of the in-person interventions.

In the event of a prolonged exercise session cancellation period due to either a disease outbreak or Penn State University recommendation to stop all exercise sessions, study staff will contact all previously-enrolled participants (pre-cancellation period) via a study-wide email and request they contact research staff via email or phone call if willing to continue participating in the exercise sessions upon the study's restart. Study staff will individually follow-up with participants who indicate an interest in continuing via email or phone call to coordinate a phone call to discuss the continuation and answer any questions the participant may have. If interested, participants will be re-invited to the exercise sessions.

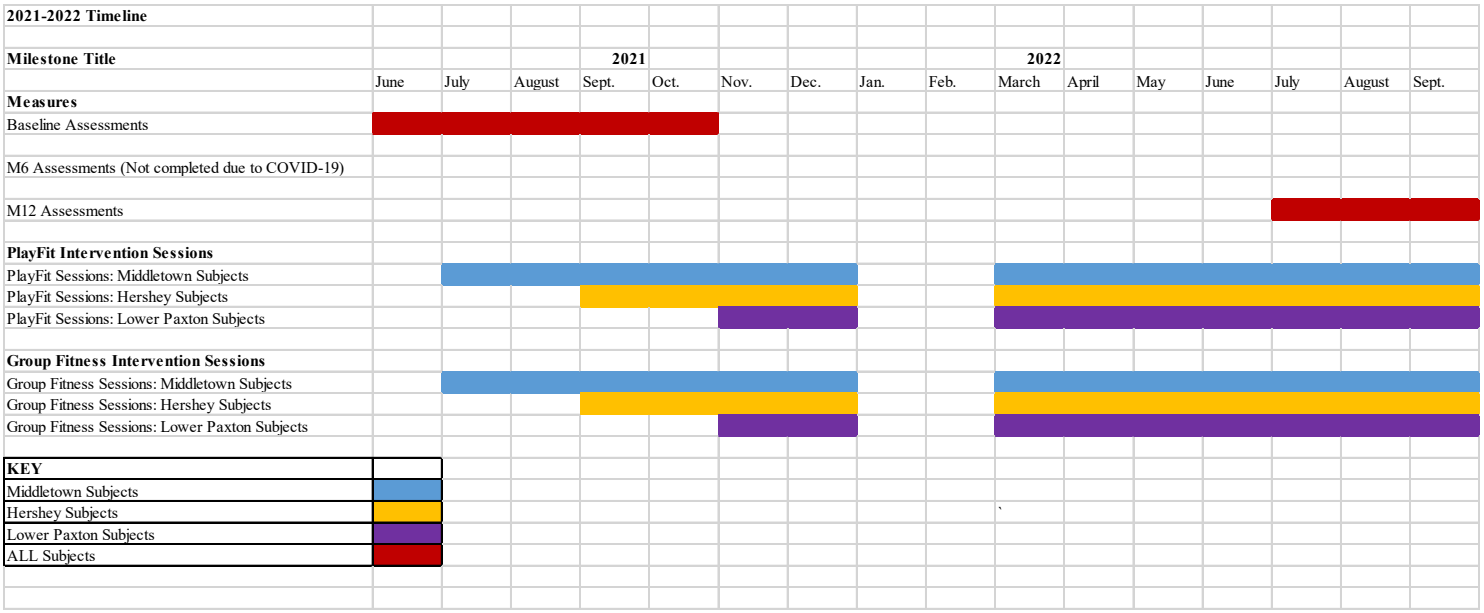
As result of an unforeseen, COVID-19-related, prolonged exercise intervention cancellation (occurring between the dates of January 10, 2022 and February 21, 2022, following Penn State University mandates to pause all in-person human subjects research) and halt in the normal delivery of the exercise intervention sessions (occurring between the dates of February 21, 2022 and April 4, 2022, in an effort to recondition subjects to the exercise interventions and mitigate the risk of injuries), participants among the 2021 cohort may be requested to continue his or her study participation beyond the 12-month time point, to achieve six (6) continuous months of normal exercise intervention delivery between the months of February 2022 and August 2022. As result of the aforementioned effects of the COVID-19 pandemic, the study will treat this 6-month period as an individual 6-month study entity, completing the listed 9- and 12-month measurements (7.2 Study Procedures, RCT) with subjects at the 3- and 6-month post-resumption of the normal delivery of exercise intervention time points, respectively.

Participants among the 2019 cohort enrolled in the trial between the months of June and December 2019. Exercise intervention-related activities began in the month of September 2019 and continued through February 2020, prior to being halted as result of the onset of the COVID-19 pandemic. 6-month study visits occurred between the months of December 2020 and February 2020, prior to being halted as result of the onset of the COVID-19 pandemic. 12-month study visits did not occur among participants in the 2019 cohort, as result of the prolonged, COVID-19-related suspension of in-person human subjects research.



Participants among the 2021 cohort primarily enrolled in the trial between the months of June and October 2021. Exercise intervention-related activities began in the month of July 2021 (among subjects first to enroll in the study) and continued through December 2021, prior to being halted as result of the COVID-19 case count surge and subsequent College of Medicine (COM) mandate to pause all in-person human subjects research. The aforementioned in-person human subjects research pause rendered the 6-month study visits not feasible (due to COM mandates), disrupting data collection activities considerably. Following a 3-month halt in the normal delivery of the exercise intervention sessions between the dates of

January 10, 2022 and April 4, 2022, as outlined above, exercise interventions continued; the normal delivery of exercise intervention sessions is set to continue through September 2022, allowing participants among the 2021 cohort to achieve six (6) continuous months of exercise intervention participation, with modified 12-month study visit procedures to occur at the conclusion of the aforementioned 6-month time period.



RCT: COVID-19 Risk Mitigation

Research study staff will instruct participants to park their vehicle in the designated Visitor Parking area(s) of the recreational space/facility. Participants will be instructed to walk from the parking area(s) to the pre-participation check-in station. All participants must bring their own water bottles and/or drinks to the project site; traditional sport hydration methods (e.g., shared water cooler) will not be provided. All participants will wear their own appropriate workout clothing, and athletic apparel shall not be shared.

Research study staff members and study participants will be required to don face masks at all times and maintain a 6-foot distance from one another at all times. At least one research study staff member will be present on-site during all project operations. Research study staff members will assume responsibility for ensuring only research staff and participant personnel are present on-site; non-participant attendance policies will be outlined with the participants in advance of the scheduled sessions. Up to a total of 30 research participants may be present at the site during each exercise session. Upon participant arrival at the project site, research study staff will require all research participants to complete a pre-participation health screening questionnaire and a temperature assessment using a touchless thermometer. Participants reporting new symptoms or with temperatures $\geq$ 100.4 degrees Fahrenheit will not be permitted to participate. Research study staff will configure the space of the check-in, health screening location, via the use of visual aids (e.g., field markers), to ensure a 6-foot distance between participants is maintained at all times.

During the exercise sessions, participants will be asked to wear a mask and adhere to the socially-distanced rulesets developed by research study staff. We have developed modified rulesets (maintain 6-feet from the player with the ball/Frisbee being defended in PlayFit, for example) to create both a socially-distanced field of play/exercise space and a socially-distanced rest area/sideline using various visual aids (e.g., field markers; designated rest areas). During the rest intervals between periods of exercise, participants will be asked to remain within his/her designated rest area. Participants will be provided his/her designated rest area after having successfully passed the pre-participation screening process. Throughout the exercise session, study staff will space themselves appropriately in an effort to conduct ongoing quality control examinations of the modified intervention, ensure masks are worn and the 6-foot ruleset protocol is adhered to as outlined, and to ensure the social distancing measures set forth in this application between study staff members are maintained at all times.

Hand sanitizer units with at least 60% alcohol will be made available for participants and research study staff. Research study staff will request participants use hand sanitizing solution upon arrival to the site and prior to touching any of the sport-game implements/exercise equipment. Whenever possible, sport-game implements/exercise equipment and other personal items shall be separated and not shared. Shared implements used to conduct the active sport-game/exercise session shall be properly disinfected between periods of activity. Research study staff have set forth a schedule for routine cleaning and disinfection. The schedule will include at minimum the cleaning of all equipment and game implements both upon arrival on-site and following the exercise session.

Feasibility – Adolescent, Major Depressive
The feasibility study is designed in two phases, among two separate populations (adolescents age 10-12 and in the 6th or 7th grade, adults being treated for major depressive disorder). First, we will conduct focus groups among adults to identify changes to the PlayFit intervention that will be needed to adapt it to the target population. Second, we will conduct a 2-month single-group study among 50 members of each group to understand the rate of attendance and whether exposure to PlayFit increases the level of physical activity (using an activity monitor worn at baseline, and monthly for 2 months) and perceived enjoyment from physical activity.

Feasibility – Older Adult
The feasibility study is designed in two phases, among adults 51-70. First, we will conduct focus groups among adults to identify changes to the PlayFit intervention that will be needed to adapt it to the target population. Second, we will conduct a 3-month single-group study among 50 members to understand the rate of attendance and whether exposure to PlayFit increases fitness (measured by $V0_2$ at the baseline and 12-week time points) as well as the level of physical activity (using an activity monitor worn at baseline and the 12-week time point) and perceived enjoyment from physical activity.

7.2 Study Procedures

RCT

MEASUREMENTS	**BaseWeb+FTF**	**3MOnline**	**6MWeb+FTF**	**9MOnline**	**12MWeb+FTF**	**MonthlyOnline**
MAIN OUTCOMES						
Aerob	X		X		X	

icFitness(in-person)			PhysicalActivityEnjoyment Scale	X	X	X	X	X		
PhysicalActivitybyAccelerometry(mailed)	X				X					
			ProgramAttendance				X		X	
			SECONDARYDEP							
MEDIATORS			ENDENTVAR							

IABLES						
Bodyweight (in-person)	X		X		X	
Blood pressure (in-person)	X		X		X	
Physical activity r		X	X	X	X	X

elated						
Injuries						
Depression, Anxiety, Loneliness	X		X		X	
International Physical Acti	X	X	X	X	X	

vityQuestionnaire			SociodemographicsX	X									
LubbenSocialNetworkScale	X		ProgramSatisfactionX		X	X	X	X	X	X	X	X	X
			Exercise	X			X			X			
COVARIATESANDOTHERVARIABLES			Isepprogrampreferences										
			PMC-C	X			X			X			

PRETIE-Q	X		X		X	
AFFEXX	X		X		X	
Competitiveness	X		X		X	
TobaccoUse	X		X		X	
ExerciseSelf-Efficacy	X		X		X	

* Participants among the 2019 cohort who are unable to attend the 6-month and 12-month in-person visit due to extreme circumstances will not complete the aerobic fitness test, physical activity by accelerometry, body weight, or blood pressure. These participants will complete the other measures via REDCap surveys online. (See 7.2.15). Additionally, participants among the 2019 cohort who opt to continue the study following a prolonged exercise session cancellation period due to either a disease outbreak or Penn State University recommendation to stop all exercise sessions will not complete the listed main outcomes measures, mediators, secondary dependent variables, or the covariates and other variables. These participants will complete injury-related measures via REDCap surveys online. Participants among the 2021 cohort, including those who opt to continue their study participation beyond the 12-month time point following an unforeseen, COVID-19 related exercise session cancellation period, will complete the listed 9- and 12-month measurements at the 3- and 6-month post-cancellation time points, respectively.

Feasibility Studies – Adolescent, Major Depressive

MEASUREMENTS	Baseline	4 weeks	8 weeks
MAIN OUTCOME			
Physical Activity by Accelerometry	X	X	X
SECONDARY OUTCOMES / COVARIATES			
Physical Activity Enjoyment Scale	X	X	X
Program Attendance	X	X	X
Physical Activity Related Injuries		X	X
Loneliness	X	X	X
Depression, Anxiety	X	X	X
Program Satisfaction		X	X
Basic Psychological Needs Satisfaction	X	X	X
Sociodemographics	X		
PMC-C *	X	X	X
PSS-10 *	X	X	X
GAD-7 *	X	X	X
PHQ-9 *	X	X	X
WHODAS 2.0 *	X	X	X
BREQ-3 *	X	X	X
PESS *	X	X	X
EMGI *	X	X	X
LCE *	X	X	X

* Measure is specific to the Major Depressive Feasibility Study.

Feasibility Studies – Older Adult

MEASUREMENTS	Baseline	6 weeks	12 weeks
MAIN OUTCOME			
Physical Activity by Accelerometry	X		X
SECONDARY OUTCOMES / COVARIATES			
Aerobic Fitness (in-person)	X		X
Blood Pressure (in-person)	X		X
Body Weight (in-person)	X		X
Berg Balance Scale (in-person)	X		X
5X Sit-to-Stand (in-person)	X		X
Physical Activity Enjoyment Scale	X		X
Program Attendance	X		X
Physical Activity Related Injuries		X	X
Loneliness (PROMIS-29)	X		X
Depression, Anxiety (PROMIS-29)	X		X
Physical Function (PROMIS-29)	X		X
Program Satisfaction		X	X
Basic Psychological Needs Satisfaction	X		X
Sociodemographics	X		
PMC-C	X		X

7.2.1 Train fitness instructors on PlayFit and Group Fitness protocols.

The training and oversight of instructors will be led by a Consultant, an exercise physiologist faculty member at Penn State with extensive experience developing, leading, and evaluating aerobic fitness programs [47, 79]. The Consultant, an exercise physiologist who creates and tests new fitness programs for Les Mills (New Zealand), the creator of Body Pump™ and other widely used programs [47, 79], will create a Group Fitness Program that is of the same MET level and duration as PlayFit. In PlayFit, the instructor gets involved in the gameplay, which helps them to create and model a non- competitive culture of play, which is similar to how a group fitness instructor exercises in sync to group fitness participants. Leaders will also be trained by research study staff on safety procedures for minimizing injuries, both orthopedic and cardiac events. The Consultant will not have access to PHI though will review summarized adherence data.

7.2.2 Rent space to hold exercise sessions.

We will visit all indoor sports facilities in our region to find times that can be reserved for our participants to exercise. The goal is to mimic a fitness center membership in the participant's community. Few people are willing to travel far for a fitness center membership so reserving space in communities will be essential to minimizing the burden of travel. We will consider hosting the program in any indoor or outdoor space that that will suit either of the programs. These will include, but not be limited to, church-owned gymnasiums, privately owned gymnasiums and outdoor public or private spaces (e.g., parks, schools).

7.2.3 Recruit participants

RCT
We will use mailed letters targeting adults 18+ living within 15 miles of the study site, using addresses from a marketing company, such as Modern Postcard and will mail the same letters to patients who receive primary care from either the Department of Family and Community Medicine or the Department of Medicine at Penn State Hershey. Our primary care surveys show that 59.1% of young and middle-aged adults whom we expect to be most interested, were interested in PlayFit. Of note, interest in PlayFit did not differ by gender or BMI, with 57.4% of obese patients interested versus 62.9% and 58.9%, respectively, of overweight and normal weight patients interested (P>.05) [61], increasing the pool of potential participants.

HOUSEHOLD MEMBER:
The same recruitment procedures will be used for RCT participants above.

FEASIBILITY STUDY:
We will use mailed letters to patients of Penn State Health, and we may use addresses from a marketing company, such as Modern Postcard, as we are in the RCT. For the adolescent feasibility study we will send letters to parents of children aged 10-12. For the feasibility study of adults aged 51-70, we will send letters to adults in that age range. For the feasibility study of adults being treated for major depressive disorder, we will send letters to adults 18+. We know that rates of depression among clinical adult populations to be 6% among men and 12% among women, so we anticipate needing more letters for this population.

7.2.4 Screening for eligibility.
The screening will be completed over the phone. Patients and household members who call will be screened by a research assistant based on the eligibility criteria (see attached screener). If the patient is eligible, we will schedule their baseline visit.

7.2.5 Physician Permission.
RCT
Before the baseline visit, which will include a maximal exercise test, a permission form (attached) will be sent to the primary care provider for signature. The permission form for household members will not include mention of the exercise testing, as this will not be part of their participation.

FEASIBILTY STUDIES: Older Adult
Before the baseline visit, which will include a submaximal exercise test, a permission form (attached) will be sent to the primary care provider for signature.

FEASIBILITY STUDIES: Adolescent, Major Depression
Permission will be required for potential participants with between 2 and 4 risk factors for heart disease, of the following 5 (sedentary lifestyle, smoking, high blood pressure, high cholesterol, early heart disease in a family member).

7.2.6 Visit 1 – Baseline Visit.
Focus Groups

60 minute small focus group discussions will be held in a community location (e.g., library, church), at a Penn State Hershey site, or via online Zoom. One of the research staff will facilitate the focus group and it will be audio recorded for data analysis. The facilitator will review the Summary Explanation of Benefits form with the subject(s) and ask individually if they have any questions. The facilitator will use the focus group/interview guide to lead the discussion/interview. The focus group guide will include the following: (1) How best to design the playfit intervention? (2) How best to interest potential participants? (3) What concerns exist

about participating? and (4) How to design a recruitment plan?

RCT

Participants will complete their first visit with research staff at Penn State Hershey, in the Physical Medicine and Rehabilitation Lab in the HCAR building or in the Lime Spring Outpatient Center in Lancaster. These visits are estimated to take 45 minutes. After the baseline visit, research staff will send RCT participants the following questionnaires, via a link to REDCap online: Physical Activity Enjoyment Scale, Depression, Anxiety, Loneliness, International Physical Activity Questionnaire, Lubben Social Network Scale, Sociodemographics, Exercise program preferences, Competetiveness, Tobacco Use, Exercise Self-Efficacy, The Preference for and Tolerance of the Intensity of Exercise Questionnaire (PRETIE-Q), The Affective Exercise Experiences (AFFEXX) and the Perceived Motor Competence Questionnaire for Children (PMC-C). After the baseline visit, research staff will send participants among the Older Adult Feasibility Study the following questionnaires, via a link to REDCap online: Physical Activity Enjoyment Scale, Depression, Anxiety, Loneliness, Sociodemographics, Basic Psychological Needs Satisfaction, and the Perceived Motor Competence Questionnaire for Children (PMC-C). These surveys should take approximately 30 minutes to complete.

Research staff will obtain signature of the informed consent document prior to the in-person visit. Before initiating any research-related activities at the in-person visit, a research staff member will take the individual's blood pressure and heart rate to screen for eligibility and safety. If blood pressure is > 160 systolic OR >100 diastolic OR heart rate is > 120 bpm, research staff will suggest the individual to see a PCP to control their blood pressure or heart rate, and if they would like to still participate in our study they can be tested again in the future. Their PCP will be sent a critical value letter including the blood pressure or heart rate values that were abnormal, and the individual will receive a critical value letter from research staff via mail. Research staff will take the participant's height and weight. Letters will also be provided for critical values on the depression and anxiety measure, as these may be clinically relevant and may warrant an evaluation.

Subjects will complete a maximal test on a treadmill using a single maximal graded treadmill test, using a Bruce protocol and ECG or heart rate monitoring [1] using a metabolic measurement system, such as a COSMED, Parvomedics or other system. Each subject will be hooked up to mask that will collect their expired gases. They will also be connected to the Quinton Q-Stress ECG machine to monitor heart rhythms or they will wear a polar heart rate monitor. Each test will use an incremental exercise test method and subjects will be instructed on how to complete each test. They will also be instructed on how to use the Borg Rated of Perceived Exertion (RPE) scale (6-20). The test will be stopped when >2 mm ST depression are noted on ECG or limited by symptoms. Speed and incline will be adjusted upwards in 3 minute increments consistent with the Bruce protocol.

Samples of gas from each 30-second period will be collected and compared to determine when steady state has been achieved, which is typically in the last 60 seconds of each 3-minute stage. The four criteria that will be used for stopping the test, consistent with when VO2Max has been achieved are 1) plateau in oxygen consumption as workload increases, 2) a respiratory exchange ratio (RER) of greater than 1.05 to 1.15 and 3) a heart rate that is within 10 to 12 beats of the age predicted maximum heart rate (220 - age) or 4) limited by symptoms or > 2mm ST elevation on ECG.

Clinical staff are present to both perform and supervise the individuals, to ensure safety. Testing will be overseen by Kristin Slavoski, exercise physiologist and Lab Director.

During this visit, subjects will be provided with explanation about how and when to wear the accelerometer. They will be asked to wear if while awake for 7 days, rather than just when they are active. They will be shown how to wear it, on the waist, so that it captures movement appropriately. Participants will be emailed or called after 48-96 hours to be sure they are wearing it and help troubleshoot in case of difficulty with the monitor.

Research coordinator will provide payment to subjects among the RCT for completing the baseline visit following receipt of the accelerometer.

Household members will not have a baseline visit. Instead, the summary explanation of benefits will be sent to the household member, and they will be given the opportunity to ask questions to study staff. Household members will not be compensated financially.

FEASIBILITY STUDIES: Older Adults

Participants will complete their first visit with research staff at Penn State Hershey, in the Physical Medicine and Rehabilitation Lab in the HCAR building. These visits are estimated to take 45 minutes. After the baseline visit, research staff will send participants the following questionnaires, via a link to REDCap online: Physical Activity Enjoyment Scale, Depression, Anxiety, Loneliness, Sociodemographics, Basic Psychological Needs Satisfaction, and the Perceived Motor Competence Questionnaire for Children (PMC-C). These surveys should take approximately 30-minutes to complete.

Research staff will obtain informed consent prior to initiating any research-related activities. Before initiating any research-related activities at the in-person visit, a research staff member will take the individual's blood pressure and heart rate to screen for eligibility and safety. If blood pressure is > 160 systolic OR >100 diastolic OR heart rate is > 120 bpm, research staff will suggest the individual to see a PCP to control their blood pressure or heart rate, and if they would like to still participate in our study they can be tested again in the future. Their PCP will be sent a critical value letter including the blood pressure or heart rate values that were abnormal, and the individual will receive a critical value letter from research staff via mail. Research staff will take the participant's height and weight. Letters will also be provided for critical values on the depression and anxiety measure, as these may be clinically relevant and may warrant an evaluation.

Subjects will complete a Five (5) Times Sit-to-Stand (5TSTS) test, using a standard height chair with a backrest, as a measure to quantify functional lower extremity strength. The 5TSTS test will require study subjects to transfer from a seated to a standing position and back to seated for a total of five (5) times; subjects will be instructed on how to complete the test prior to administration. The test will be stopped when a total of five (5) transfers is achieved, unless limited by symptoms.

Subjects will complete a fourteen (14)-item balance assessment, using a standard height chair

with a backrest as well as a standard height step, as a measure of balance and physical function. The balance assessment will require study subjects to transfer from a seated to a standing position, using several variations of transfer (Berg Balance Scale); subjects will also perform additional, functional balance activities (Berg Balance Scale). Subjects will be instructed on how to complete the test prior to administration. The test will be stopped when completion all fourteen (14) balance items is achieved, unless limited by symptoms.

Subjects will complete a submaximal test using a stepping tool, using an ECG or heart rate monitoring [1] metabolic measurement system, such as a COSMED, Parvomedics or other system. Each subject will be hooked up to mask that will collect their expired gases. They will also be connected to the Quinton Q-Stress ECG machine to monitor heart rhythms or they will wear a polar heart rate monitor. Each test will require the study subjects to step up-and-down a step for a total of 3-minutes; subjects will be instructed on how to complete the test prior to administration. They will also be instructed on how to use the Borg Rated of Perceived Exertion (RPE) scale (6-20). The test will be stopped when a total of 3-minutes is achieved, unless limited by symptoms.

Clinical staff are present to both perform and supervise the individuals, to ensure safety. Testing will be overseen by Kristin Slavoski, exercise physiologist and Lab Director.

During this visit, subjects will be provided with explanation about how and when to wear the accelerometer. They will be asked to wear if while awake for 7 days, rather than just when they are active. They will be shown how to wear it, on the waist, so that it captures movement appropriately. Participants will be emailed or called after 48-96 hours to be sure they are wearing it and help troubleshoot in case of difficulty with the monitor.

Research coordinator will provide payment to subjects among the Older Adult Feasibility study for completing the baseline visit following receipt of the accelerometer.

FEASIBILITY STUDIES: Adolescent, Major Depression

Prior to the initial in-person visit, participants (and at least one parent in the case of the adolescent feasibility study) will review the consent form via phone call with study staff for 30 minutes. During that time, they will explain the study and complete the informed consent procedures. Of note, potential participants for the Adolescent Feasibility Study will be requested to sign consent upon arrival at the project site, prior to the beginning of any research-related activities. At the initial in-person visit, they will provide an explanation about how and when to wear the accelerometer. After the informed consent procedures are complete, research staff will send participants the following questionnaires, via a link to REDCap online and based on the target population:

Adolescents: Shortened Physical Activity Enjoyment Scale (S-PACES), Basic Psychological Needs Satisfaction, the PROMIS Depression and Anxiety Scale, Brief Loneliness Scale, PMC-C and Sociodemographics.

Adults with Major Depressive Disorder: Physical Activity Enjoyment Scale (PACES), Hamilton Rating Scale for Depression (HAM-D), Sociodemographics, PMC-C, Brief Loneliness Scale, the PMC-C, PSS-10, GAD-7, PHQ-9, WHODAS 2.0, BREQ-3, PESS, EMGI, and the LCE. Of note, the HAM-D will be completed over the phone, by either Dr. Auer, a clinical psychologist, or a research staff member trained by Dr. Auer, rather than being completed online.

7.2.7 Communicating Abnormal Stress Test Results

In the event of the participant experiencing an elevation of > 2 mm in ST segments on the ECG, Dr. Silvis will communicate these results by phone with the participant and care provider that

signed the permission form.

7.2.8 Randomization.

Once eligible participants who sign the informed consent and completed the baseline questions, research staff at each site will randomize the participant into one of two groups (group fitness, PlayFit) in a one-to-one ratio based on the following stratification factors: age (over and under 35) and gender. The randomization will be performed through REDCap, but participant will not be informed of the group assignment until the accelerometer has been received and the baseline online surveys have been completed. At that point, a project staff member will contact the participant to review the randomization assignment (group fitness, PlayFit) and orient the participant to the program, by explaining how sessions tend to run, what to bring, reviewing possible locations, discussing frequently asked questions and answering any additional question the participant may have. Additionally, the participant will be given the option to install the TeamSnap phone application in order to receive exercise session confirmation and cancellation notifications.

7.2.9 Group A. PlayFit – up to 4 times weekly

This condition includes up to four times weekly, instructor-led, modified sports. Participants will be instructed to begin at a low pace and will gradually increase their intensity over time. PlayFit sessions start with a brief warm up period of "catch", with a partner, using the piece of sports equipment of the day (e.g., ball, Frisbee), followed by alternating 10-minute periods of play and short water breaks. The warm-up and breaks encourage socializing. PlayFit classes, similar to Group Fitness classes (above), will be offered at multiple times during the day, similar to offerings at health clubs, to overcome scheduling barriers. The instructor who oversees the session will provide a minimal level of instruction on the basics of each sport during the warm-up, as well as explain 1-2 key movements per sport (e.g., using the instep of the foot for passing in soccer). The sports include soccer, using a lightweight volleyball, and 4 other modified sports that all use the rules of Ultimate Frisbee (Team Handball, Netball, Ultimate Football), including: 1) two steps only after catching, 2) change possession after dropping, 3) no contact with passer, and 4) no goalie (if using a net). Each day, the instructor will divide players randomly into sides and the instructor will also play, as in Group Fitness, to assure that the culture of non-competitive play is kept. If the score is lop-sided (e.g., 6-0), the instructor will switch two team members during one of the breaks. A brief period of "catch" at the end allows for cool-down and more socializing. Of note, the same fitness instructors will instruct PlayFit and Group Fitness, to control for the instructor effects. Sport modifications are as below. In addition, attendance will be recorded by the group leader at each session. Sessions will be offered up to 4 times per week. Participants will be sent a reminder notification for each confirmed, instructor-led session via the TeamSnap phone application.

To assess intervention fidelity (i.e., that the amount and intensity of physical activity provided in each exercise condition is the same), a random sample of participants in each group and at each site will wear an ActiGraph GTX-3 accelerometer during up to five (5) 1-hour sessions of PlayFit or Group Fitness. Random numbers will be assigned to each participant at site "A" in intervention condition "1" using Excel. For example, a group of 40 participants at site "Hershey and" intervention condition "PlayFit" will each be assigned a random number from 1-40. The first 20% of participants at each site (i.e., those assigned numbers 1-8) will wear an accelerometer during that exercise session. Study staff will bring the devices to the session and provide them to the participants randomly selected for that exercise session. Following the 1-hour session, study staff will collect the devices and ask the participant to rate the perceived intensity level of the exercise session. The participant may decline to wear the device. For participants that decline to wear the device, study staff will go to the next random participant on their list and ask this participant to wear the device during the 1-hour session.

COVID-19 Risk Mitigation: Physical Activity
Both research study staff members and study participants will be required to don face masks and maintain a 6-foot distance from one another at all times. Up to a total of 30 research participants may be present at the site during each exercise session. Research study staff will configure the

exercise space to ensure a 6-foot distance between participants is maintained at all times.

During the exercise session, participants will be asked to wear a mask and adhere to the socially-distanced rulesets developed by research study staff. We have developed modified rulesets (maintain 6-feet from the player with the ball/Frisbee being defended in PlayFit, for example) to create both a socially-distanced field of play and a socially-distanced rest area/sideline using various visual aids (e.g., field markers; designated rest areas). During the rest intervals between periods of exercise, participants will be asked to remain within his/her designated rest area. Participants will be provided his/her designated rest area after having successfully passed the pre-participation screening process. Throughout the exercise session, study staff will space themselves appropriately in an effort to conduct ongoing quality control examinations of the modified intervention, ensure masks are worn and the 6-foot ruleset protocol is adhered to as outlined, and to ensure the social distancing measures set forth in this application between study staff members are maintained at all times.

Research study staff will request participants use hand sanitizing solution prior to touching any of the sport-game implements/exercise equipment. Whenever possible, sport-game implements/exercise equipment and other personal items shall be separated and not shared. Shared implements used to conduct the active sport-game shall be properly disinfected between periods of play. Research study staff have set forth a schedule for routine cleaning and disinfection. The schedule will include at minimum the cleaning of all equipment and game implements both upon arrival on-site and following the exercise session.

Feasibility Studies
All participants in the Adolescent and Major Depressive Feasibility Studies will get access to PlayFit several times weekly for 2 months. All participants in the Older Adult Feasibility Study will get access to PlayFit several times weekly for 3 months. Based on the results of the Focus Groups for each applicable Feasibility Study, small changes may be made to the PlayFit intervention, to adapt the intervention to the target population. Those changes will be presented for IRB approval after the focus groups have completed, and before the 2- or 3-months of PlayFit participation. For example, for adults over 50, we intend to reduce the length of play periods for the first month, as adults over 50 have lower levels of fitness. Among participants under age 50, we start with 6 minute periods and increase to 8 minutes in two weeks and then to 10 minute periods in two additional weeks. Among participants over age 50, we anticipate starting with 4 minute periods for the first two weeks, increasing the time to reach 10 minute periods by an additional two weeks.

In the Older Adult Feasibility study, staff will contact participants at the conclusion of each exercise intervention session via an online REDCap survey questionnaire and request they complete a 3-item, qualitative survey questionnaire. The qualitative survey questionnaire will aim to identify both the participant's level of program enjoyment to-date and level of interest in recommending the exercise program to a friend, family member, or colleague.

Sport	Equipment Modification	Field Modification (Basketball Court)	Rule Modification (+ sides chosen randomly)
Soccer	Lightweight underinflated volleyball, 4’ pop-up net	90’ long x 50’ wide (normally 300’ x 150’)	5-7 per side (normally 11). No goalie.
European Netball	Lightweight Beginner Basketball	Half Court (50’ x 42’) (normally full-court: 60’ x 92’)	No contact, two-step rule, no dribbling, change possession if dropped.
Team Handball	6” Dodge Ball 4’ pop-up net	90’ long x 50’ wide (normally 300’ x 150’)	No contact, two-step rule, change possession if dropped. No goalie.
Ultimate Frisbee	Lightweight Soft Frisbee	90’ long x 50’ wide (normally 300’ x 150’)	No contact, two-step rule, change possession if dropped.
Ultimate Football	Nerf Football	90’ long x 50’ wide (normally 300’ x 160’)	No contact, two-step rule, change possession if dropped.
Kickball	Larger bases to accommodate multiple runners (foam mats)	Little league field (60 foot bases versus 90 feet for older players)	All players kick each inning, offensive team pitches, no throwing at runners, no force outs.

7.2.10 Group B. Group Fitness – up to 4 times weekly

This condition is designed to represent a standard of care, as instructor-led group exercise classes are common at most fitness centers. Many fitness centers include multiple group exercise classes, although these differ somewhat from location to location. Participants will be instructed to begin at a low pace and will gradually increase their intensity over time. One of our Consultants is an exercise physiologist who creates and tests new fitness programs for Les Mills (New Zealand), the creator of Body Pump™ and other widely used programs [47, 79]. While men have been historically less interested in group fitness, this is no longer the case. The International Health, Racquet & Sports Club Association reported in 2016 that 38% of group fitness participants were men [44]. The Consultant has selected a set of 5-7 MET classes from common fitness centers to match the expenditure level of PlayFit. These classes will be included in a week-by-week plan for participants in the Group Fitness condition. In addition, subjects will be encouraged, at baseline, to ask questions of the fitness instructor at the beginning and/or end of the classes, as this is the standard of care at fitness centers. In months 1-2, participants will be encouraged to join the back of the group and leave early (e.g., after 30 min), until their fitness has improved. These classes will be offered at multiple times during the day, similar to offerings at health clubs, to overcome scheduling barriers. As group fitness classes are attended more by women than men, to limit the possibility of lower adherence in men to group fitness, the Consultant will be designing the intervention, based on years of designing programs for Les Mills and running her own studio, so that it is as gender-neutral (and attractive to men) as possible. Group fitness classes are more commonly attended by women, but her experience shows that several movements can be incorporated that make the fitness classes more interesting to men: strength training, athletic movements (e.g., high knee runs, block jumps) and martial arts movements (e.g., kicks, jabs). These tactics tend not to alienate women, so they will be used to make the programs more satisfying to men, as groups will be equally comprised of men and women. Attendance will be recorded by the group leader at each session. Sessions will be offered up to 4 times per week. Participants will be sent a reminder notification for each confirmed, instructor-led session via the Team Snap phone application.

To assess intervention fidelity (i.e., that the amount and intensity of physical activity provided in each exercise condition is the same), a random sample of participants in each group and at each site will wear an ActiGraph GTX-3 accelerometer during up to five (5) 1-hour sessions of PlayFit or Group Fitness. Random numbers will be assigned to each participant at site "A" in intervention condition "1" using Excel. For example, a group of 40 participants at site “Hershey and” intervention condition “PlayFit” will each be assigned a random number from 1-40. The first 20% of participants at each site (i.e., those assigned numbers 1-8) will wear an accelerometer during that exercise session. Study staff will bring the devices to the session and provide them to the participants randomly selected for that exercise session. Following the 1-hour session, study staff will collect the devices and ask the participant to rate the perceived intensity level of the exercise session. The participant may decline to wear the device. For participants that decline to wear the device, study staff will go to the next random participant on their list and ask this participant to wear the device during the 1-hour session.

COVID-19 Risk Mitigation: Physical Activity
Both research study staff members and study participants will be required to don face masks and maintain a 6-foot distance from one another at all times. Up to a total of 30 research participants may be present at the site during each exercise session. Research study staff will configure the exercise space to ensure a 6-foot distance between participants is maintained at all times.

During the exercise session, participants will be asked to wear a mask and adhere to the socially-distanced rulesets developed by research study staff. We have developed modified rulesets to create both a physically-distanced exercise space and a physically-distanced rest area using various visual aids (e.g., field markers; designated rest areas). During the rest intervals between periods of exercise, participants will be asked to remain within his/her designated rest area.

Participants will be provided his/her designated rest area after having successfully passed the pre-participation screening process. Throughout the exercise session, study staff will space themselves appropriately in an effort to conduct ongoing quality control examinations of the modified intervention, ensure masks are worn and the 6-foot ruleset protocol is adhered to as outlined, and to ensure the social distancing measures set forth in this application between study staff members are maintained at all times.

Research study staff will request participants use hand sanitizing solution prior to touching any of the sport-game implements/exercise equipment. Whenever possible, sport-game implements/exercise equipment and other personal items shall be separated and not shared. Shared implements used to conduct the active sport-game shall be properly disinfected between periods of play. Research study staff have set forth a schedule for routine cleaning and disinfection. The schedule will include at minimum the cleaning of all equipment and game implements both upon arrival on-site and following the exercise session.

7.2.11 Exercise session cancellation policy

Exercise sessions may be canceled if the investigative team determines that there is an increased risk to the safety of the participants. This includes, but is not limited to, no available trained instructor, severe weather, disease outbreak, and any recommendations to stop in-person visits from the Office of the Senior Vice President (OSVPR) of Penn State University. Exercise session cancellation notifications will be sent to participants via the Team Snap phone application.

As result of a prolonged exercise session cancellation period due to a disease outbreak as well as Penn State University's recommendation to stop all exercise sessions, study staff will contact all subjects among the 2021 cohort whom have had their 12-month exercise participation timeline impacted and request they contact research staff via if willing to continue their participation, to achieve 12-months of exercise participation.

Study staff will follow-up with these participants individually via phone call to coordinate a review of the additional information to the study. Following a review of the additional information to the study, study staff will request participants to confirm his or her understanding of the information and provide electronic written consent. At the conclusion of the phone call, study staff will communicate all materials reviewed to the participant via email.

7.2.12 Pre-participation Health and Safety Screening

RCT + Feasibility

The remote component of the pre-participation health and safety screening will be completed over-the-phone 48 hours in advance of a study visit. Participants will be pre-screened using the Penn State Senior Vice President for Research – Screening for Exposure to COVID-19 symptom questionnaire. Participants reporting new symptoms will not be permitted to participate.

The on-site component of the pre-participation health and safety screening will be completed upon the participant's arrival to the program activity site. Participants will be pre-screened using the Penn State Senior Vice President for Research – Screening for Exposure to COVID-19 symptom questionnaire. Additionally, participants will be pre-screened using a digital, touchless thermometer. Participants reporting new symptoms or with temperatures ≥ 100.4 degrees Fahrenheit will not be permitted to participate.

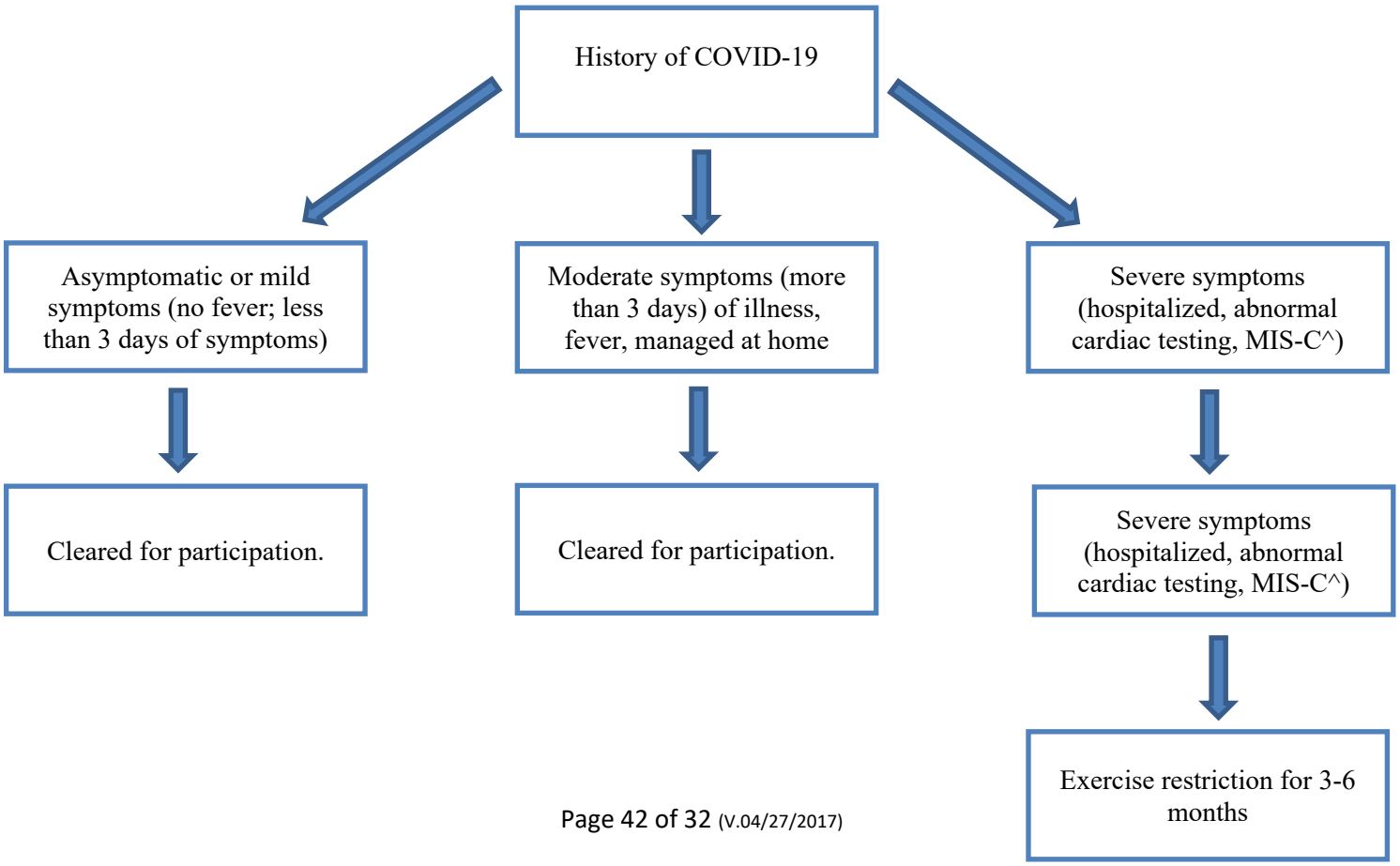
Pre-participation, health and safety screening data will be recorded within the PlayFit Attendance Longitudinal REDCap Project by research staff (Exercise Instructors). Exercise Instructors will input health and safety assessment data into the REDCap Project at the conclusion of each exercise intervention session.

Exercise Instructors will be prompted to confirm all of the participants who attended the session did not indicate any new symptoms or record temperatures ≥ 100.4 degrees Fahrenheit. In the event that a study participant indicates a new symptom or records a temperature ≥ 100.4 degrees Fahrenheit, the Instructor will be prompted to document the occurrence within the attendance sheet. Additionally, the Exercise Instructor will be prompted—via online REDCap—to notify the Research Project Manager (RPM) of the occurrence via direct email; REDCap will be configured to send an automated email notification to the RPM, too, in a direct effort to ensure the occurrence is documented immediately.

The RPM will document any Exercise Instructor correspondence as well as automated REDCap alert notifications received via the PlayFit Attendance Longitudinal Project within the PlayFit-Participants Project. The RPM will document the content within the Health & Safety (H&S) Contact Form.

Research coordinators will receive automated REDCap alert notifications via the PlayFit-Participants Project upon the RPM documenting content within the H&S Contact Form Data Collection Instrument. Research coordinators will initiate contact with the individual(s) who either reported a new symptom or recorded a temperature ≥ 100.4 degrees Fahrenheit at the project site to outline the 14-day isolation protocol and, if applicable, initiate the Return to Play algorithm screening (Figure 1), if the individual discloses a diagnosis of or positive test for COVID-19. In the event a participant discloses a positive test for or diagnosis of COVID-19, research staff will notify all other study participants affiliated with the COVID-positive individual's exercise site.

Figure 2. Return to Play after COVID-19 Algorithm



Algorithm based on current recommendations from: 1) PlayFit Study DSMB Members; 2) Study Physician, Dr. Matthew Silvis, MD; and 3) the ACC, AMSSM, and NFHS. These recommendations are subject to change as more evidence on COVID-19 myocarditis becomes available. Any subject who develops signs of clinical instability should be directed to the emergency department. If never symptomatic, the 14-day period begins at the time of a positive test. If there is return of any symptoms, the 14-day asymptomatic period restarts.

7.2.13 Participant Engagement and Re-Engagement

To keep participants engaged, participants will be contacted by study staff following their first session to answer any questions and address any concerns. In this conversation, study staff will address any barriers identified by the participant that could possibly prevent the participant from attending future sessions.

In an effort to re-engage participants who have stopped attending sessions, study staff will attempt to contact them up to five times if they have not attended a session for 14 or more days. Participants who have not attended a session for between 14 and 21 days will be treated as acute stopped attenders, and participants who have not attended a session for 21 or more days will be treated as chronic stopped attenders; both will be contacted up to five times. Chronic stopped attenders will be sent a 2-item, feedback survey via REDCap on the fifth and final contact attempt.

In the event of a prolonged exercise session cancellation period due to either a disease outbreak or Penn State University recommendation to stop all exercise sessions, study staff will contact all participants via a study-wide email and request they contact research staff via email if willing to participate in a 15-minute, qualitative debriefing interview. Study staff will select up to 45 participants (of varying levels of intervention participation, as outlined below) who are first to respond. Study staff will follow-up with these participants individually via email or phone call to coordinate the interview. Study staff will conduct the interview via phone call and will ask participants to provide verbal consent to audio record the interview. If the individual declines to be recorded, study staff will continue the phone call interview, entering responses into REDCap manually. The interview will aim to identify the both the participant's level of program enjoyment to-date and level of interest in returning to the intervention following the prolonged exercise session cancellation period. Study staff will aim to conduct interviews with participants of varying levels of intervention participation: 1) participants who never attended an exercise session; 2) participants who stopped attending sessions; and 3) participants who actively attended the sessions at the onset of the prolonged cancellation period. If interested, participants will be compensated for his/her time. At the conclusion of the phone call, participants will be asked to participate in an optional monthly, multi-item survey questionnaire designed to assist the research team in gaining a better understanding of how community perceptions and thoughts regarding comfort level in/willingness to return to organized activity following the prolonged exercise cancellation period are progressing over time. If the individual is interested in participating in the survey, study staff will utilize REDCap to administer the survey on a fixated, monthly basis, up until 04/01/2021. Participants will be compensated by Greenphire ClinCard at each time point for completing his/her survey.

7.2.14 Survey of Injury and Satisfaction

RCT

At the end of each project month, subjects will complete a brief survey via REDCap online, of adverse events (e.g., injuries) and program satisfaction. This should take no more than 20 minutes at Month 1, and no more than 5 minutes in all other months. Household members will also complete these surveys, as it is deemed essential to monitor participant safety.

FEASIBILITY STUDIES – Adolescent, Major Depressive

At the 4- and 8-week time points, subjects will complete a brief survey via REDCap online, of adverse events (e.g., injuries) and program satisfaction. This should take no more than 20 minutes at Week 4, and no more than 5 minutes in Week 8.

FEASIBILITY STUDIES – Older Adult

At the 6- and 12-week time points, subjects will complete a brief survey via REDCap online, of adverse events (e.g., injuries) and program satisfaction. This should take no more than 20 minutes at Week 6, and no more than 5 minutes in Week 12.

7.2.15 3 and 9 Month Follow-Up Online REDCap Survey.

RCT Only

At 3 and 9 months, subjects will be emailed to complete the following measures via surveys in RECap: Physical Activity Enjoyment Survey, Adverse Events and Injury Survey, Program Satisfaction Survey and International Physical Activity Questionnaire. This is expected to take 10 minutes. Household members will not complete these surveys.

Feasibility Studies – Adolescent, Major Depressive

At the 4- and 8-week time points, research staff will send participants the same questionnaires that were sent following the completion of informed consent procedures, via a link to REDCap online, in addition to the Injury questionnaire (Stathokostas) that is measured in the RCT. They will also be sent an accelerometer to wear for 7 days, the same as at the start of the study, which they will return by mail.

Feasibility Studies – Older Adult

At the 12-week time point, research staff will send participants the same questionnaires that were sent following the completion of informed consent procedures, via a link to REDCap online, in addition to the Injury questionnaire (Stathokostas) that is measured in the RCT. At the 12-week time point, they will be provided an accelerometer to wear for 7-days, which they will return by mail.

The 12-week follow-up visit will be identical to the baseline visit, other than the consent process – which will not be repeated. Research staff will send participants the following questionnaires via REDCap online: Physical Activity Enjoyment Scale, Depression, Anxiety, Loneliness, Sociodemographics, Basic Psychological Needs Satisfaction, and the Perceived Motor Competence Questionnaire for Children (PMC-C). These surveys should take approximately 30 minutes to complete.

During the visits, which will take place in the Department of Physical Medicine and Rehabilitation Lab in the the HCAR building, research staff will take the participant's blood pressure, height and weight, administer two (2) balance and physical function assessments, and complete a submaximal stress test, using the identical protocol as in the above baseline visit.

These visits are estimated to take 45 minutes. Research coordinator will provide payment for completing the 12-week visit following receipt of the accelerometer.

Research participants who are unable to attend an in-person visit due to extreme circumstances will still complete the surveys via REDCap online. These circumstances include, but are not limited to, travel burden, severe weather, disease outbreak, and any recommendations by Penn State University or Penn State Milton S. Hershey Medical Center to stop in-person visits.

7.2.16 6 and 12 Month Follow-Up Visit.

RCT

The 6 and 12 month follow-up visits will be identical to the baseline visit, other than the consent process, which will not be repeated, as well as the 7-day accelerometer wear trial, which may be completed in lieu of an in-person study visit, should research staff determine the participant is either unable or unwilling to attend an in-person visit. Research staff will send participants the following questionnaires via REDCap online: Physical Activity Enjoyment Scale, Depression, Anxiety, Loneliness, International Physical Activity Questionnaire, Lubben Social Network Scale, Sociodemographics, Exercise program preferences, Competetiveness, Tobacco Use, Exercise Self-Efficacy, The Preference for and Tolerance of the Intensity of Exercise Questionnaire (PRETIE-Q), The Affective Exercise Experiences (AFFEXX) and the Perceived Motor Competence Questionnaire for Children (PMC-C). These online surveys should take approximately 30 minutes to complete. Household members will not complete these visits and surveys.

During the visits, which will take place in the Department of Physical Medicine and Rehabilitation Lab in the the HCAR building, research staff will take the participant's blood pressure, height and weight and a maximal stress test will be completed, using the identical protocol as in the above baseline visit. These visits are estimated to take 45 minutes. Research coordinator will provide payment for completing the 6 month visit and for completing the 12 month visit following receipt of the accelerometer.

Research participants who are unable to attend an in-person visit due to extreme circumstances will still be requested to complete both the 7-day accelerometer wear trial as well as surveys via REDCap online. These circumstances include, but are not limited to, travel burden, severe weather, disease outbreak, and any recommendations by Penn State University or Penn State Milton S. Hershey Medical Center to stop in-person visits.

7.2.17 2021 Cohort: COVID-19 Design Modifications

As described within subsection 7.1 (COVID-19 Design Modifications), an unforeseen exercise intervention cancellation occurred between the dates of January 10, 2022 and February 21, 2022, following Penn State University mandates to pause all in-person human subjects research. In addition, a follow-up halt in the normal delivery of the exercise intervention sessions occurred between the dates of February 21, 2022 and April 4, 2022, in an effort to recondition subjects to the exercise interventions and mitigate the risk of injuries. Following the aforementioned 3-month period, subjects among the 2021 cohort were requested to continue his or her study participation, in an effort to achieve six (6) continuous, uninterrupted months of standard delivery exercise intervention. As result of the aforementioned effects of the COVID-19 pandemic, this 6-month period will be treated as an individual 6-month data collection period entity, with subjects completing the listed 9- and 12-month measurements (7.2 Study Procedures, RCT) at the 3- and 6-month post-resumption of the normal delivery of exercise intervention time points, respectively.

7.2.18 Video Collection for Quality Control and for Recruitment Facilitation

At regular intervals during the project, sessions will video recorded. All participants will be asked to sign a standard Media Consent for Communications Media during the consent process, though they will not be required to sign to be part of the project. During sessions that will be recorded, subjects will be asked if they specifically do not want to be on camera during that session. If so, subjects will be moved to an area that will not be video recorded. Sessions will be video recorded, using a digital video camera that records to removable media. Recording will be done either by study staff or a professional videographer who will be accompanied by study staff. Media will be stored on the network. Videos to facilitate recruitment will first be shared with all participants who are shown on camera and scenes will be removed if participants are not comfortable with the footage shown being made public. Scenes from these videos will be added to the recruitment video, posted at www.exercisestudy.org. Videos will also be reviewed by project staff to measure adherence to the intervention.

7.3 Duration of Participation

RCT
All participants will be in the study for 12 months.

Feasibility Studies: Adolescent, Major Depressive

All participants will be in the study for approximately 2 months, including a one-time focus group (adults currently being treated for major depressive disorder only) and then the 2 months of PlayFit participation, which will start approximately one month later.

Feasibility Studies: Older Adult

All participants will be in the study for approximately 3 months, including a one-time focus group and then the 3 months of PlayFit participation, which will start approximately one month later.

8.0 Subject Numbers and Statistical Plan

8.1 Number of Subjects

Focus Groups:

We will enroll 100 subjects

RCT:

We will enroll up to 470

subjects.

Feasibility Studies:

We will enroll up to 50 subjects in each of the three studies, or up to 150 total. We hypothesize that access to PlayFit will increase the minutes of moderate-vigorous PA from 10 minutes per day (SD=20) at baseline to 20 minutes per day (SD=30) after 3 months. As there is a dose-response relationship between MVPA and mortality, a doubling of MVPA should be expected to lead to a 60% reduction in mortality [41]. To achieve 80% power for these differences (with an alpha of <0.05), we will enroll up to 50 subjects at baseline, anticipating losses to follow-up of no more than 8 (16%) after 8 weeks, leaving up to 42 for analysis.

8.2 Sample size determination

We hypothesize that average weekly indoor sports facility attendance will be similar between PlayFit and Group Fitness (2.5 times per week) at 6 months, but at 12 months, attendance at PlayFit will be higher than at Group Fitness (2.5/week v. 1.5/week), which will lead to significant fitness differences. The power and sample size calculations are based on three pieces of background data: First, that supervised group fitness activities, among untrained adults, appear to increase V02max by at least 4 units over 12 months. Casla and colleagues, for example, recruited breast cancer patients for a twice weekly group fitness program and observed a mean V02max gain from an average of 26.5 to an average of 32.6 over 12 weeks [80]. Second, that PlayFit, which includes short sprints typical of sports, will increase V02max by at least 2.5 units more than Group Fitness, owing to greater attendance. Hammami and colleagues, in a meta-analysis of 28 studies, observed fitness gains of 7-14% for recreational soccer [81] and, in 2015, Milanović noted a 24% increase due to 3 times weekly soccer among untrained adults [82]. We have conservatively estimated a 10% increase in fitness among PlayFit participants. Oja and colleague conducted a meta-analysis of various sports interventions and observed a mean change in V02max of 4.11 (95% CI; 1.10-7.12) in the 5 studies of recreational soccer [83], similar in design to how the 5 PlayFit games are played. Third, without intensive contacts, long-term adherence to typical fitness programs is poor. Dellavigna and colleagues observed that, among 7,752 fitness center members followed for three years, the average member attended 4.3 times per month, far below recommendations for improving fitness [64].

8.3 Statistical methods

The analysis of the main outcome measure will be performed by intent-to-treat, in which changes between baseline and twelve (12) full months of exercise intervention participation will be compared by conditions. Student's t-test will be used, though adjustment may be needed for any variables not controlled through randomization. If it is determined that the groups, by chance, are significantly different on other covariates, then we will include those covariates in secondary analyses.

9.0 Confidentiality, Privacy and Data Management

9.1 Confidentiality

9.1.1 Identifiers associated with data and/or specimens

See the Research Data Plan Review Form

9.1.1.1 Use of Codes, Master List

See the Research Data Plan Review Form

9.1.2 Storage of Data and/or Specimens
See the Research Data Plan Review Form

9.1.3 Access to Data and/or Specimens
All project personnel (PI and project staff will have access to the data.

9.1.4 Transferring Data and/or Specimens
Not applicable. Data will not be transferred.

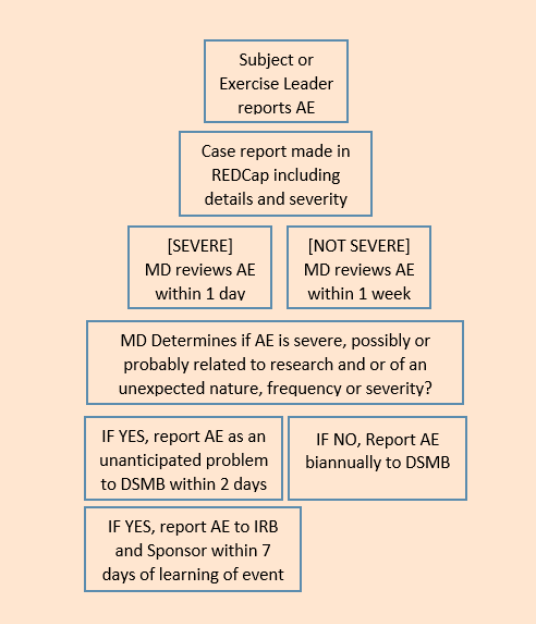
9.2 Subject Privacy
See the Research Data Plan Review Form

10.0 Data and Safety Monitoring Plan

We will work closely with our Data and Safety Monitoring Board (DSMB) to conduct biannual reviews of our procedures and data that is collected. All issues raised will be expected to be resolved no later than the time of the next meeting.

10.1 Data that are reviewed
The DSMB will review no less than the following elements to assure compliance with the study protocol and to assure the quality of the data collected. They will review: consent forms, adverse events, outcome measures (e.g., V02max, accelerometry). Findings will be presented at a meeting attended by investigators and staff so all team members are aware and can be actively involved in a possible remediation plan.

10.2 Method of collection of safety information
Adverse events will be captured by surveys each month, using links to surveys in REDCap. Adverse events that occur during the stress testing will also use the Adverse Event form, which includes details on the outcome of the event as well as the type of injury.



10.3 Frequency of data collection
As above, adverse event data will be collected beginning in the first month and then it will continue monthly.

10.4 Individuals reviewing the data
The DSMB will include one biostatistician, one cardiologist, and two primary care providers.

10.5 Frequency of review of cumulative data
Biannually, the DSMB will meet and review AE frequency and severity, by condition and make a determination as to whether any changes should be made to the study protocol, consent or adverse event reporting procedure.

10.6 Statistical tests
Chi-Square tests will be used to determine differences in specific adverse events between conditions, as these variables are percentages.

10.7 Suspension of research

As above, the DSMB will review all serious AEs within 2 days and identify an action plan and report that to the sponsor and the IRB within 7 days. The DSMB plan may include stopping the study, either temporarily or permanently.

11.0 Risks

Focus Groups

There is the possibility that sensitive information is shared beyond the meeting room, either by directly communicating information by another subject or by the loss of the electronic file containing the recording of the discussion. To minimize these risks, specific mention is made during the explanation that sensitive information should not be disclosed which, given that the topic is physical activity that is done in public, this should not limit what is learned in the groups. Also, the staff member will remind subjects not to discuss what is learned outside of the group and any files will be stored on password protected computers and destroyed at the end of the study. Further, subjects will not be referred to by name during the discussion to minimize the potential loss of confidentiality from the recording becoming lost.

RCT and Feasibility Studies

Exercise: The exercise program follows recommended guidelines for physical activity, but there is always the possibility that any increase in physical activity may result in an injury. Like any exercise program, it can cause any of the following: pain and soreness in muscles and joints, pain and soreness in feet, neck and spine, ligament injury or sprain, fracturing a bone, concussion, shortness of breath, dizziness, abnormal heart responses, nausea, vomiting, a temporary elevation in blood pressure, excessive fatigue, dehydration, chest pain, heat exhaustion, low blood glucose, heart attack, abnormal heart rhythm, or a fatal event. To minimize risk, each exercise site is led by a member of the study team that is trained in CPR and has an emergency kit.

Stress Testing (RCT only): Risks from stress testing include the following: Abnormal heart responses to the exercise, muscle soreness or muscle pulls resulting from the exercise, dizziness, nausea, vomiting, chest pain, heart attack, stroke or death due to performing physical exercise, temporary elevation of blood pressure. It is also possible for the ECG to show an abnormality that later tests show is false.

Loss of confidentiality: There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your data stored electronically will be maintained to the degree permitted by the technology used. The exercise groups will be encouraged to keep any personal information shared during group discussions confidential. Absolute confidentiality cannot be guaranteed.

Questionnaires: If you are uncomfortable answering questions on the surveys, you are free to skip any questions that you would prefer not to answer.

Randomization (RCT only): You may have a preference for one group over the other and be assigned to the group you're less enthusiastic about. To participate you need to be willing to try the group you're assigned to, but this may be a disappointment to you.

The risks to subjects in this study are judged to be minor. The main foreseeable risks to participating include injury from exercise testing, from exercising and from loss of confidentiality.
There are risks from stress testing, though the subjects are all considered low-risk, as higher-risk subjects are excluded. The stress testing will be overseen by an ACSM Certified Clinical Exercise Physiologist and/or a staff member possessing a Master's degree in Exercise Physiology/Kinesiology.

Loss of confidentiality is a risk but precautions will be taken to prevent this from happening. All PHI (in both paper and electronic form) will be separated from data collected from subjects. Paper documents and electronic information containing data will have only the subject's code/ID number. Research staff will use REDCcap (a password-protected and encrypted electronic research data program) to both collect and store data. Staff will have some paper copies of research documents and data (e.g., surveys), that will be stored in a locked cabinet in Dr. Rovniak's research office. Any data collected on paper will then be input into Redcap. PHI will be located in Redcap.

12.0 Potential Benefits to Subjects and Others

12.1 Potential Benefits to Subjects

There is no guaranteed benefit from participating in the study. A participant may benefit by becoming more fit, lose weight, improve their blood pressure and blood sugar due to the exercises.

12.2 Potential Benefits to Others

The hope is that if PlayFit outperforms Group Fitness that fitness centers will offer programs similar to PlayFit and that individuals who are given the option would learn the results of the study and choose a program similar to PlayFit when starting an exercise program.

13.0 Sharing Results with Subjects

We will communicate any critical values of a clinical measure (e.g., blood pressure, depression and anxiety screen) to subjects.

14.0 Subject Stipend (Compensation) and/or Travel Reimbursements

Focus Groups

$40

RCT:

All RCT participants enrolled in 2021 will receive a total of $175 in Greenphire ClinCard payment throughout the study.
- $25 Greenphire ClinCard payment after having returned the accelerometer for the baseline visit
- $50 Greenphire ClinCard payment after having returned the accelerometer for the 6-month follow-up
- $100 Greenphire ClinCard payment after having returned the accelerometer for the 12-month follow-up

RCT participants who participate in the qualitative debriefing interview (outlined within "7.2.12 Participant Engagement and Re-Engagement") will receive payment by a $25 Greenphire ClinCard.

RCT participants who participate in the post-qualitative debriefing interview, monthly survey (outlined within "7.2.12 Participant Engagement and Re-Engagement") will receive payment by a $10 Greenphire ClinCard at each time point.

Feasibility Studies:

Participants may receive up to $120 total payment by Greenphire ClinCard throughout the study.

-$40 ClinCard for participation in the 90-minute focus group (Depression, Older Adult only)
-$20 ClinCard for baseline data collection, online surveys, phone-based survey in depression feasibility study, and accelerometer wearing
-$20 ClinCard for Week 4 accelerometry and online surveys (phone-based survey in depression feasibility study) (Adolescent, Depression only)
-$40 ClinCard for 2-month data collection, online surveys (phone-based survey in depression feasibility study) and accelerometer wearing (Adolescent, Depression only)
-$40 ClinCard for 3-month data collection, online surveys, in-person study visit, and accelerometer wearing (Older Adult only)

15.0 Economic Burden to Subjects

15.1 Costs

There are no economic costs to subjects for participating.

15.2 Compensation for research-related injury

It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injurie will be charged to subjects or their insurance carriers.

16.0 Resources Available

16.1 Facilities and locations

Focus Groups

Focus group discussions will be held in a community location (e.g., library, church), at a Penn State Hershey site, or via online Zoom.

Feasibility Studies

Eexercise sessions will be held in a community location, such as a church, school, fitness center or indoor sports facility.

RCT

Baseline, 6 and 12 month visits will be held in the Department of Physical Medicine and Rehabilitation Lab in the HCAR building, where exercise testing equipment exists.

16.2 Feasibility of recruiting the required number of subjects

We have the ability to send recruitment letters to over 100,000 adult patients ages 18-50, the group most likely to respond, who are seen by the Departments of Family and Community Medicine and the Division of General Internal Medicine. This means that we need to recruit less than 0.5% of the target population. As getting more exercise is a key resolution of adults in the US and the study uses an active control group, we believe that many people will be quite interested in participating.

16.3 PI Time devoted to conducting the research

Dr. Rovniak will devote 10% time to the study, to monitor the progress of participant recruitment and enrollment and will hold weekly meetings with research staff and co-investigators. She will notify the NIH Project Officer (Boyington) of any important issues.

16.4 Availability of medical or psychological resources

In case of emergencies, the PI (a primary care physician) will contact the subject and recommend or refer to appropriate medical or psychological resources.

16.5 Process for informing Study Team

The PI is responsible for creating and updating a working protocol of study procedures and for training the research staff on the protocol.

17.0 Other Approvals

17.1 Other Approvals from External Entities

We will get approvals from the community exercise site locations that we can hold the exercise programs at their location for the duration of the study. The site locations will include indoor sports facilities such as those that youth soccer is held.

17.2 Internal PSU Committee

Approvals Check all that apply:

☐ Anatomic Pathology – Hershey only – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of HRP-902 - Human Tissue For Research Form on the "Supporting Documents" page in CATS IRB. This form is available in the CATS IRB Library.

☐ Animal Care and Use – All campuses – Human research involves animals and humans or the use of human tissues in animals

☐ Biosafety – All campuses – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).

☐ Clinical Laboratories – Hershey only – Collection, processing and/or storage of extra tubes of body fluid specimens for research purposes by the Clinical Laboratories; and/or use of body fluids that had been collected for clinical purposes, but are no longer needed for clinical use. Upload a copy of HRP-901 - Human Body Fluids for Research Form on the "Supporting Documents" page in CATS IRB. This form is available in the CATS IRB Library.

☐ Clinical Research Center (CRC) Advisory Committee – All campuses – Research involves the use of CRC services in any way.

☐ Conflict of Interest Review – All campuses – Research has one or more of study team members indicated as having a financial interest.

☐ Radiation Safety – Hershey only – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload a copy of HRP-903 - Radiation Review Form on the "Supporting Documents" page in CATS IRB. This form is available in the CATS IRB Library.

☐ IND/IDE Audit – All campuses – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.

☐ Scientific Review – Hershey only – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. NOTE: Review by the Penn State Hershey Cancer Institute Scientific Review Committee is required if the study involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website at: http://www.pennstatehershey.org/web/irb/home/resources/investigator

18.0 Multi-Site Research

18.1 Communication Plans

Not applicable, not a multi-site research project

18.2 Data Submission and Security Plan

Not applicable, not a multi-site research project

18.3 Subject Enrollment

Not applicable, not a multi-site research project

18.4 Reporting of Adverse Events and New Information

Not applicable, not a multi-site research project

18.5 Audit and Monitoring Plans

Not applicable, not a multi-site research project

19.0 Adverse Event Reporting

19.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

20.0 Study Monitoring, Auditing and Inspecting

20.1 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

21.0 Future Undetermined Research: Data and Specimen Banking

21.1 Data and/or specimens being stored
Not applicable.

21.2 Location of storage
Not applicable.

21.3 Duration of storage
Not applicable.

21.4 Access to data and/or specimens
Not applicable.

21.5 Procedures to release data or specimens
Not applicable.

21.6 Process for returning results
Not applicable.

22.0 References